N.J.A.C. TITLE 8
CHAPTER 33

Certificate of Need:
Application and Review Process

Authority
N.J.S.A. 26:2 H-1 et seq.

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New Jersey Department of Health & Senior Services
Division Of Health Care System Analysis
Certificate of Need and Acute Care Licensure Program

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SUBCHAPTER 1. GENERAL PROVISIONS

8:33-1.1 Purpose and scope

(a) The purpose of these rules is to implement the provisions of the Health Care Facilities Planning Act, P.L. 1971, c.136, as amended by P.L. 1978, c.83, the Health Care Cost Reduction Act, P.L. 1991, c.187, the Health Care Reform Act, P.L. 1992, c.160, and the Certificate of Need Reform Act, P.L. 1998, c. 43. These rules may be amended as necessary, in accordance with N.J.S.A. 52:14B-1 et seq., the Administrative Procedure Act, and N.J.A.C. 1:30, Rules for Agency Rulemaking, to best implement the statutory provisions and to reflect changing economic and systemic conditions within the health care system.

(b) These rules apply to the initiation, construction and/or expansion of all health care facilities and services as identified in the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq. and/or Appendix Exhibits I through 3 of this chapter, incorporated herein by reference. Applicants for certificates of need are advised that the policies, standards, and criteria set forth in this chapter are in addition to, and not in limitation of, any other applicable certificate of need authorities, specifically including, but not limited to, those in N.J.S.A. 26:2H-1 et seq., the service-specific health planning rules, any applicable licensing authorities, or any specific conditions imposed upon facilities or services by the Commissioner in their particular certificate of need approvals.

(c) All inquiries regarding certificate of need matters should be directed to:

Certificate of Need and Acute Care Licensure Program
New Jersey State Department of Health and Senior Services
PO Box 360, Room 403
Health-Agriculture Building
John Fitch Plaza
Trenton, New Jersey 08625-0360
(609) 292-6552 and 292-7228

8:33-1.2 General statements of public policy and rules of general application

(b) It is the public policy of the State that access to health care services of the highest quality are of vital concern to the public health. Recognizing the significant changes in the economics of the health care system since the inception of the certificate of need program, decisions as to most health care services, acquisition of medical technology, and expansion of facilities can best be made by the health care provider. The appropriate role of the State with respect to services no longer subject to certificate of need is that of licensure of facilities and services to ensure the quality of care. For reasons of maintaining the quality of certain health care services, a limitation of the proliferation of such services may continue to be essential to protect the viability of the services as well as the providers now rendering them, to protect the role of such institutions as urban hospitals, whose importance to the Statewide health care system is indisputable, and to guard against the closing of important facilities and the transfer of services from facilities in a manner which is harmful to the public interest. Pursuant to N.J.S.A. 26:2H-1, to protect and

promote the health of the inhabitants of the State, the Department shall have the central, comprehensive responsibility for the development and administration of the State's policy with respect to health planning for all such health care facilities and services. Based on the particular needs of the State, this plan may include limiting the proliferation of certain health care services to preserve the viability of existing providers and urban hospitals, which play a vital role in the Statewide health care delivery system. The Department also must guard against the closing of important institutions and the transfer of services from facilities in a manner that is harmful to the public interest. All such health care facilities and services shall be subject to the provisions established herein.

(b) The Commissioner, to implement the provisions and purposes stated above, shall have the power to inquire into the accessibility to and availability of health care services and the operation of health care facilities and to conduct periodic inspections of such facilities with respect to the fitness and adequacy of the premises, equipment, personnel, rules and bylaws and the adequacy of financial resources and resources of future revenues.

(c) No certificates of need shall be issued unless the action proposed in the application for such certificate is necessary to provide required health care in the area(s) to be served, can be financially accomplished and maintained, licensed in accordance with applicable licensure regulations, will not have an adverse economic or financial impact on the delivery of or access to health care services in the region or Statewide, and will contribute to the orderly development of adequate and effective health care services. In making such determinations there shall be taken into consideration the availability of facilities or services which serve as alternatives or substitutes, the need for special equipment and services in the area, the adequacy of financial resources and sources of present and future revenues, the availability of sufficient human resources in the several professional disciplines, the accessibility to and availability of health care services to low income persons, and such other factors as may be established by regulation. In the case of an application by a health care facility established or operated by any recognized religious body or denomination, the needs of the members of such religious body or denomination for care and treatment in accordance with their religious or ethical convictions may be considered to be public need.

(d) Certificate of need applications shall be reviewed for conformance with the rules in effect on the date the application is accepted for processing or deemed complete for processing, as applicable.

(e) Recommendations concerning certificates of need shall be governed and based upon the principles and considerations set forth in these rules, as well as applicable State laws and rules.

(f) Certificates of need shall be issued by the Commissioner based upon criteria and standards promulgated by the Commissioner and approved by the Health Care Administration Board. (See N.J.A.C. 8:33 and the applicable chapter for specific services.) If any application is denied, the applicant may request a hearing pursuant to the Administrative Procedure Act, P.L. 1968, c. 410 (N.J.S.A.52:14B-1 et seq. and 52:14F-1 et seq.), and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1 in accordance with N.J.S.A. 26:2H-9. Requests for a hearing shall be made to the Department within 30 days of receipt of notification of the Commissioner's

action. The Department shall arrange for a hearing within 60 days of receipt of a request, and after such hearing the Commissioner or his or her designee shall furnish the applicant with the hearing examiner's written recommendations and reasons therefor. The Commissioner, within 30 days of receiving all appropriate hearing records, shall make his or her determination, which shall be a final agency decision.

(g) Projects involving building construction or renovations require submission of architectural plans to the Department of Community Affairs for approval prior to initiating building construction or renovations, in accordance with this chapter and the Department's licensing rules, regardless of whether the project requires a certificate of need or is exempt from the certificate of need requirement. At project completion, written notification and a copy of the certificate of occupancy shall be submitted to the Department of Community Affairs for final approval of the project.

(h) Written notification or application for a license, as applicable, shall be submitted to the Department's Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable, prior to the planned use of the beds, services or facility, in accordance with this chapter and the Department's licensing rules.

(i) Application for a license on forms prescribed by the Department shall be filed with the Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable, for approval prior to any transfer of ownership of beds, service or facility, in accordance with this chapter and the Department's licensing rules.

(j) No health care facility shall be operated unless it shall possess a valid license issued by the Department pursuant to N.J.S.A. 26:2H-1 et seq. The establishment of a new health care facility, the expansion of beds and services, and renovations or additions to health care facilities require approval from the Department's Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable, prior to operation/occupancy of the beds, services or areas.

8:33-1.3 Definitions

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise.

"Accepted for processing" means an application, subject to N.J.A.C. 8:33-5, has been determined by the Department as eligible to be entered into the applicable review cycle.

"Adolescent acute psychiatric beds" means licensed psychiatric beds in a designated and separate unit of a licensed general, psychiatric or special hospital, established for the provision of intensive treatment to persons generally between the ages of 13 and 18 who are experiencing an acute episode of a primary psychiatric disorder and have been medically evaluated to require the services of a specifically designated unit.

"Adult acute psychiatric beds" means licensed psychiatric beds in a designated and separate unit of a general, psychiatric or special hospital, established for the provision of intensive evaluation, stabilization and treatment of persons 18 years of age and older who are experiencing an acute episode of a primary psychiatric disorder. Patients are admitted under voluntary status.

"Adult closed acute psychiatric beds" means licensed psychiatric beds in a designated and separate unit of a general, psychiatric, or special hospital for the provision of treatment services for persons experiencing an acute episode of a psychiatric disorder. All such persons are referred by a designated psychiatric screening center and may be admitted voluntarily or involuntarily if they are determined to be mentally ill and dangerous to self or others.

"Adult intermediate psychiatric beds" means licensed psychiatric beds in a separate and designated area in a general, psychiatric or special hospital for the provision of intensive psychiatric evaluation and treatment services as part of a comprehensive psychiatric and psychosocial rehabilitation program, and which are appropriate for individuals aged 18 and above who are experiencing an acute episode of a psychiatric disorder and who require a comprehensive and specialized treatment program that cannot be fully provided within a short-term acute psychiatric setting. Admissions to the intermediate psychiatric unit or facility have an average length of stay which is generally greater than the average length of stay for adult acute psychiatric units in New Jersey and less than 45 days.

"Advanced life support" (ALS) means an advanced level of prehospital, interhospital, and emergency service care which includes basic life support functions, cardiac monitoring, cardiac defibrillation, telemetered electrocardiography, intravenous therapy, administration of specific medications, drugs and solutions, use of adjunctive ventilation devices, trauma care, and other techniques and procedures authorized by the Commissioner, pursuant to N.J.S.A. 26:2K-7.

"Ambulance service" means the provision of emergency or non-emergency medical care and transportation by certified personnel in a vehicle, which is designed and equipped to provide medical care at the scene and while transporting sick and/or injured persons to or from a medical care facility or provider.

"Applicant" means an individual, a partnership, a limited liability partnership, a corporation (including associations and joint-stock companies), a limited liability corporation, a State, or a political subdivision or instrumentality (including a municipal corporation) of a State that will be the licensed operator of the proposed service, facility or equipment, which will have overall responsibility for the health care service to be provided.

"Assisted living program" means the provision of or arrangement for meals and assisted living services, when needed, to the tenants (also known as residents) of publicly subsidized housing which because of any Federal, State, or local housing laws, regulations or requirements cannot become licensed as an assisted living residence. An assisted living program may also provide staff resources and other services to a licensed assisted living residence and a licensed comprehensive personal care home.

"Assisted living residence" means a facility that is licensed by the Department to provide apartment-style housing and congregate dining and to assure that assisted living services are available when needed, to four or more adult persons unrelated to the proprietor. Apartment units offer, at a minimum, one unfurnished room, a private bathroom, a kitchenette, and a lockable door on the unit entrance.

"Bed capacity" means the total number of beds, listed by health care service within the facility, which are recognized on the facility's current license.

"Bloodless surgery" means the performance of surgery in a general hospital without the use of blood transfusion, including, but not limited to, adult cardiac surgery and exclusive of pediatric cardiac surgery, solid organ transplantation, high risk perinatal, and trauma surgery.

"Burn center" means a general hospital that provides the same comprehensive burn care services as required of a burn unit. In addition, a burn center provides intensive and comprehensive in-service training and education for all burn care personnel and includes a research component.

"Burn program" means a general hospital that provides therapy to burn patients, which includes fluid resuscitation and electrolyte balance, hydroptherapy, debridement, escharotomy, and shock prevention.

"Burn unit" means a general hospital that has beds committed solely to burn care, a large and diversified physician staff and nursing staff that rotate solely in this service. A burn unit shall provide electrocardiograph-oscilloscope defibrillation, cardiac output monitoring, physical therapy-hydrotherapy and occupational therapy.

"Central service facility" means a health care facility, regulated by the Department, providing essential administrative and clerical support service to two or more direct providers of health care services in a region and which may also include some direct provision of health care services.

"Change in cost" means any cost in excess of the total approved cost in the most recent certificate of need approval for the project.

"Change in project scope" is defined as a deviation from the approved certificate of need, which results in a change in any one of, but not limited to, the following:

1. Number of beds by service;

2. Change in complement of major movable equipment, that is, cardiac catheterization;

3. Array of services;

4. Service area;

5. Access or availability to the approved project;

6. Population served including the percentage of Medicaid and medically indigent required to be served as a condition of certificate of need approval; or

7. Square footage.

"Children's acute psychiatric beds" means licensed psychiatric beds in a designated unit of a licensed general, psychiatric or special hospital, for the provision of intensive treatment of persons generally under the age of 13 who are experiencing an acute episode of a psychiatric disorder and have been medically evaluated to require acute psychiatric inpatient services.

"Commissioner" means the State Commissioner of Health and Senior Services.

"Community perinatal center" means a licensed hospital designated within a Maternal and Child Health Service Region as one of the following:

1. "Community perinatal center-basic" means a licensed general hospital that provides services to uncomplicated maternity and normal newborn patients in accordance with the scope of functions delineated in its formal letter of agreement with the regional perinatal center. This hospital is characterized by physically separated facilities for labor, delivery, and newborn care, with cesarean section capability within the perinatal suite. The hospital must also provide supportive care for infants returned from regional or community perinatal center-intensive care facilities. Such a facility shall provide care to patients expected to deliver neonates greater than 2,499 grams and at least 36 weeks gestational age.

2. "Community perinatal center-intermediate" means a licensed general hospital which provides care to a minimum of 800 complicated maternity patients and neonates in accordance with the scope of functions delineated in its formal letter of agreement with the regional perinatal center. Such a facility shall provide care to patients expected to deliver neonates greater than 1,499 grams and at least 32 weeks gestational age.

3. "Community perinatal center-intensive" means a licensed general hospital which provides care to complicated maternity patients and neonates in accordance with the scope of functions delineated in its letter of agreement with the hospital and the Regional Perinatal Center. Such a facility shall provide care to patients expected to deliver neonates greater than 999 grams and at least 28 weeks gestational age.

"Comprehensive personal care home" means a facility that is licensed by the Department to provide room and board and to assure that assisted living services are available when needed, to four or more adults unrelated to the proprietor. Residential units in comprehensive personal care homes house no more than two residents and have a lockable door on the unit entrance.

"Comprehensive rehabilitation" means services offered by a licensed rehabilitation hospital and characterized by the coordinated delivery of multidisciplinary care intended to achieve the goal of maximizing the self-sufficiency of the patient.

"Construction" means the erection, building, alteration, reconstruction, improvement, renovation, extension or modification of a health care facility, including fixed equipment, the inspection and supervision thereof; and the studies, surveys, designs, plans, working drawings, specifications, procedures, and other actions necessary thereto.

"Deemed complete for processing" means an application, subject to N.J.A.C. 8:33-4, that, determined to be complete by the Department, has been entered into the applicable review cycle.

"Deferral" means a suspension of the review of a submitted application for a limited period of time.

"Demonstration project" generally refers to a health care service, technology, equipment or modality not currently available in the State or which targets unique institutional circumstances or the needs of underserved populations. A demonstration project requires a certificate of need as specified at N.J.A.C. 8:33-3.11.

"Department" means the New Jersey State Department of Health and Senior Services.

"Discontinuance" means any health care facility which has closed or substantially ceased operation of any of its beds, facilities, services, or equipment for a period of two succeeding years.

"Emergency medical service helicopter" means a service which provides aeromedical emergency care and transportation by rotowing aircraft and is licensed in accordance with N.J.A.C. 8:41.

"Expedited review cycle" means the period of time from the date the application is submitted to the expedited review process through the date a decision is rendered by the Commissioner.

"Expedited review process" means the review by the Department of a certificate of need application meeting certain specified criteria. Such a review process does not include a review by the State Health Planning Board.

"Fixed equipment" means equipment which is attached to the physical plant of a facility.

"Full review cycle" means the period of time from the date the application is submitted to the full review process through the date a decision is rendered by the Commissioner.

"Full review process" means the review of an application by the State Health Planning Board, as well as the Department.

"General hospital" means a hospital which maintains and operates organized facilities and services as approved by the Department for the diagnosis, treatment or care of persons suffering from acute illness, injury or deformity and in which all diagnosis, treatment and care are

administered by or performed under the direction of persons licensed to practice medicine or osteopathy in the State of New Jersey.

"General long-term care" means a long-term care bed for which there is no restriction imposed by statute (for example, subacute long-term care), certificate of need approval requirements (for example, pediatric long-term care, specialized long-term ventilator care, specialized long-term care of patients with severe behavior management problems) or stipulations and/or licensure standards that would limit the type of nursing home patient who may occupy the bed or the type or length of nursing home care which may be provided to the occupant of the bed.

"Health care facility" means the facility or institution, whether public or private, engaged principally in providing services for health maintenance organizations, diagnosis or treatment of human disease, pain, injury, deformity or physical condition, including, but not limited to, a general hospital, special hospital, mental hospital, public health center, diagnostic center, treatment center, rehabilitation center, extended care facility, skilled nursing home, intermediate care facility, assisted living residence, comprehensive personal care facility, tuberculosis hospital, chronic disease hospital, maternity hospital, outpatient clinic, dispensary, home health care agency, residential health care facility and bioanalytical laboratories (except as specifically excluded hereunder) or central services facility serving one or more such institutions but excluding institutions that provide healing solely by prayer and excluding such bioanalytical laboratories as are independently owned and operated, and are not owned, operated, managed or controlled in whole or in part, directly or indirectly by any one or more health care facilities and the predominant source of business of which is not by contract with health care facilities within the State of New Jersey and which solicit or accept specimens and operate predominantly in interstate commerce.

"Health care service" means the preadmission, outpatient, inpatient, and postdischarge care provided in or by a health care facility, and such other items or service as are necessary for such care, which are provided by or under the supervision of a physician for the purpose of health maintenance or diagnosis or treatment of human disease, pain, injury, disability, deformity, or physical condition, including, but not limited to, nursing service, home care nursing and other paramedical service, ambulance service, service provided by an intern, resident in training or physician whose compensation is provided through agreement with a health care facility, laboratory service, medical social service, drugs, biologicals, supplies, appliances, equipment, bed and board, but excluding services provided by a physician, nurse practitioner, clinical nurse specialist, certified nurse midwife or physician assistant, in his or her private practice, unless the service is the subject of a health planning regulation as defined in this section, adopted by the Department of Health or involves the acquisition of major moveable equipment as specified herein, and services provided by volunteer first aid, rescue and ambulance squads as defined in the New Jersey Highway Safety Act of 1971, P.L. 1971, c.351.

"Home health agency" means a facility that is licensed by the Department to provide preventive, rehabilitative, and therapeutic services to patients in the patient's home or place of residence. All home health agencies shall provide nursing, homemaker-home health aide, and physical therapy services.

"Hospital system" means a group of licensed general hospital facilities owned or controlled by the same legal entity.

"Inner city cardiac satellite demonstration project" means a cooperative expansion of invasive therapeutic cardiac services within a hospital system, whereby a satellite hospital within the system is permitted to provide invasive therapeutic cardiac services already provided by an inner city hospital within the same hospital system and which meets all of the criteria set forth in this chapter and N.J.A.C. 8:33E.

"Inner city hospital" means a general hospital which is located in a city with a population which is greater than 50,000 (or in a city with population greater than 10,000 located in a county with population density greater than 2,500 persons per square mile) and in which more than 10 percent of families in the city have income levels which are below the Federal poverty line, as determined in accordance with 42 U.S.C. § 9902(2).

"Invasive cardiac services" means cardiac catheterization which is the insertion of a thin, flexible tube (catheter) into a vein or artery and guiding it into the heart for purposes of determining cardiac anatomy and function.

"Invasive therapeutic cardiac services" means the full array of therapeutic cardiac interventional procedures that includes, but is not limited to, coronary artery bypass graft (CABG), percutaneous transluminal coronary angioplasty (PTCA), and complex electrophysiology studies (EPS).

"Long term acute care hospital-within-a-hospital" means a hospital established in accordance with the standards imposed by the United States Department of Health and Human Services at 42 C.F.R. Part 412 et al. that occupies space in a building also used by another hospital and is licensed as a special hospital in accordance with N.J.A.C. 8:43G-38.

"Long term acute care hospital-freestanding" means a hospital established in accordance with the standards imposed by the United States Department of Health and Human Services at 42 C.F.R., Part 412 et al. that is a physically separate self-contained facility and is licensed as a special hospital in accordance with N.J.A.C. 8:43G-38.

"Major moveable equipment" means cardiac catheterization equipment.

"Maternal and child health consortium" means a nonprofit organization that is licensed as a central service facility by the Department as specified in N.J.A.C. 8:33C, and incorporated under Section 501(c)(3) of the United States Internal Revenue Code.

"Medically underserved" means segments of the population whose utilization of health care services is disproportionately low to their presence in the population as adjusted to account for their need for such services. Medically underserved includes, but is not limited to, racial and ethnic minority populations, migrant workers, the handicapped, Medicaid recipients, and the medically indigent, defined as those individuals lacking third party insurance coverage whose

income is less than or equal to 200 percent of the United States Department of Health and Human Services Income Poverty Guidelines, 42 U.S.C. § 9902(2).

"Minor moveable equipment" means equipment that does not fall within the definition of major moveable equipment stated herein.

"Mobile intensive care unit" (MICU) means a specialized emergency medical service vehicle staffed by mobile intensive care paramedics or mobile intensive care nurses trained in advanced life support nursing and operated for the provision of advanced life support services under the direction of an authorized hospital.

"Modernization/renovation" means the alteration, expansion, major repair, remodeling, replacement, and renovation of existing buildings, and the replacement of obsolete equipment of existing buildings.

"Null and void," "nullification," and "nullify" means the Commissioner's revocation of a certificate of need prior to the expiration of the certificate.

"Operator" of a health care facility means the person or entity which is the holder of the facility license and which has the ultimate responsibility for the provision of health care services in the facility in accordance with applicable legal and professional standards.

"Pediatric intensive or critical care" means a general hospital unit in which special equipment and skilled personnel are concentrated to provide immediate and continuous attention to pediatric patients who, because of surgery, shock, trauma, serious injury or life threatening conditions, require intensified comprehensive observation, and care.

"Pediatric long-term care" means a facility, distinct nursing unit, or program which is dedicated for occupancy by patients under age 20 who require long-term care services.

"Pediatric service" means provision of services by a general hospital to pediatric patients.

"Perinatal" means the period from the 20^{th} week of gestation through the neonatal period.

"Person" shall include a corporation, limited liability corporation, company, association, society, firm, partnership, limited liability partnership, and joint stock company, as well as an individual.

"Planning region" means the county(ies) where (a) facility(ies), service(s), or bed(s) subject to CN is located and/or proposed to be located, in accordance with the approved CN, and contiguous counties.

"Principal" means any individual, partnership, or corporation with an ownership interest in the operating entity of a health care facility or service, or a general or managing partner in a limited partnership.

"Project cost" means costs submitted in those dollars which would be needed to complete the project over the anticipated period of construction, if construction were to begin at the time of certificate of need submission.

"Provider of health care" means an individual:

1. Who is a direct provider of health care service in that the individual's primary activity is the provision of health care services to individuals or the administration of health care facilities in which such care is provided and, when required by State law, the individual has received professional training in the provision of such services or in such administration; or

2. Who is an indirect provider of health care in that the individual:

i. Holds a fiduciary position with, or has a fiduciary interest in, any entity described in subparagraph 2ii(2) or subparagraph 2ii(4) below; provided, however, that a member of the governing body of a county or any elected official shall not be deemed to be a provider of health care unless he is a member of the board of trustees of a health care facility or a member of a board, committee or body with authority similar to that of a board of trustees, or unless he participates in the direct administration of a health care facility; or

ii. Received, either directly or through his or her spouse, more than one-tenth of his or her gross annual income for any one or more of the following:

(1) Fees or other compensation for research into or instruction in the provision of health care services;

(2) Entities engaged in the provision of health care services or in research or instruction in the provision of health care services;

(3) Producing or supplying drugs or other articles for individuals or entities for use in the provision of or in research into or instruction in the provision of health care services; or

(4) Entities engaged in producing drugs or such other articles.

"Psychiatric hospital" means a hospital licensed by the Department which assures the provision of comprehensive specialized diagnosis, care, treatment and rehabilitation where applicable on an inpatient basis for patients with primary psychiatric diagnoses.

"Regional perinatal center" means a licensed general hospital designated within a Maternal and Child Health Service Region that is required to provide care to high risk mothers and neonates. Such a facility shall provide consultation, referral, transport and consultation to its regional affiliates.

"Rehabilitation hospital" means a hospital licensed by the Department to provide comprehensive rehabilitation services to patients for the alleviation or amelioration of the disabling effects of illness. Comprehensive rehabilitation services are characterized by the

coordinated delivery of multidisciplinary care intended to achieve the goal of maximizing the self-sufficiency of the patient. A rehabilitation hospital is a facility licensed to provide only comprehensive rehabilitation services or is a distinct unit providing only comprehensive rehabilitation services located within a licensed health care facility.

"Research projects" are projects whose scope of inquiry and activity are exclusively limited to the execution of a research protocol which when it involves human subjects must be approved by an Institutional Review Board; whose services and interventions are provided to approved study subjects alone; who do not bill for or receive reimbursement for the services, equipment, or interventions provided through the research; and whose services, equipment, or interventions are not competing with and do not negatively impact upon licensed providers of health care services in the State, as determined by the Commissioner.

"Satellite hospital" means, for purposes of N.J.A.C. 8:33E-3.11, a general hospital that is not the inner city hospital which is the subject of an inner city cardiac demonstration project, but which shall be a general hospital within the same hospital system as the inner city hospital at issue.

"Service area" means a geographic area, generally a county, within which the facility or service is located. However, definitions of service areas specified in approved planning rules shall take precedence over this general definition.

"Special hospital" means a hospital which maintains and operates organized facilities and services as approved by the Department for the diagnosis, treatment or care of persons suffering from acute illness, injury or deformity in which comprehensive specialized diagnosis, care, treatment and rehabilitation are administered by or performed under the direction of persons licensed to practice medicine or osteopathy in the State of New Jersey, where applicable, on an inpatient basis for one or more specific categories of patients as approved by the Department.

"Special psychiatric beds" means licensed psychiatric beds within any separate unit or section of a licensed general, psychiatric or special hospital which are utilized for the treatment of an identified target population of any age demonstrated to require a specialized program of treatment for acute psychiatric disorders. Examples include units designated to provide services to persons with eating disorders, geriatric services and with dual psychiatric/substance abuse diagnoses. Admissions to the unit or facility should have an average length of stay that reflects the level of active medical care for each category of special psychiatric beds and, as a guideline, does not exceed 60 days.

"Specialized long-term care" means a program of care provided in licensed long-term care beds for patients who require technically complex treatment with life supporting equipment or who have serious problems accessing appropriate nursing home care due to the specialized treatment required by their medical diagnoses and level of functional limitation.

"Specialty acute care children's hospital" means a general hospital, designated by the Commissioner pursuant to a statutory mandate, that provides diagnostic and specialty treatment services for children and is licensed in accordance with N.J.A.C. 8:43G-22.

"State" means the State of New Jersey.

"State Health Planning Board" means the board established pursuant to N.J.S.A. 26:2H-5.7, to conduct certificate of need review activities.

"Statewide restricted admissions facility" means a nonprofit nursing home owned and operated by a religious or fraternal organization that serves only members of that organization and their immediate families and meets the specific requirements set forth in N.J.A.C. 8:33H.

"Subject of a health planning regulation" means any health care service identified in the Appendix, Exhibit 1.

"Teaching hospital" means, for purposes of N.J.A.C. 8:33-3.11(c), a general hospital engaged in a graduate medical education residency program in cardiology approved by a nationally recognized credentialing organization.

"Termination" means a certificate of need is not extended by the Commissioner beyond its expiration date.

"Total capital cost" means all costs associated with the proposed project including studies and/or surveys; architect, engineer, legal fees; plans and specifications; supervision and inspection of site and buildings; demolition, renovation, construction; fixed and major moveable equipment, purchase of land and buildings; lease and/or rentals; developmental and/or start up costs, but excluding carrying and financing cost and/or fees, interest and debt service reserve fund. Total capital cost excludes any contingency amounts.

"Trauma services" means the treatment of wounds or injuries of sufficient severity to require treatment at a Level I or Level II trauma center, as measured by the immediate threat of death imposed by the injury, the presence of injuries to multiple systems, Injury Severity Score or other trauma scoring systems, and/or the application of appropriate trauma triage decision criteria.

"Total project cost" means all costs associated with the proposed project, including all capital costs, carrying and financing costs, net interest on borrowings during construction, debt service reserve fund. Total project cost excludes any contingency amounts.

"Withdrawal" means a voluntary written request by a certificate of need applicant to the Department to cease any further review of a submitted application submitted before the Commissioner acts on the application. Such a request shall be considered final by the Department and no further consideration or review shall be given to the "withdrawn" application.

SUBCHAPTER 2. APPLICABILITY OF CERTIFICATE OF NEED REQUIREMENTS

8:33-2.1 Types of Review

There will be two types of review of certificate of need applications: full review, as described in N.J.A.C. 8:33-4.1(a), and expedited review, as described in N.J.A.C. 8:33-4.1(b). The full review process shall apply to all certificate of need applications not specifically identified herein as meeting the criteria for expedited review. The review process shall apply as specified in Exhibit 3 of the Appendix, incorporated herein by reference.

8:33-2.2 Determination of a health care facility or service

(a) It is incumbent upon all health care facilities and services to comply with the certificate of need requirements set forth in statute and rules promulgated pursuant thereto. If such automatic compliance is not forthcoming, the Commissioner, consistent with the "public policy of the State that access to health care services of the highest quality are of vital concern to the public health" (N.J.S.A. 26:2H-1) and in accordance with the definitions of a health care facility and a health care service, as specified in N.J.S.A. 26:2H-2 and 26:2H-7, shall determine whether a proposed or existing system or modality of health care delivery constitutes a health care service or health care facility subject to certificate of need requirements. If so designated, such facility shall be subject to all of the provisions of the Health Care Facilities Planning Act (N.J.S.A. 26:2H-1 et seq.) and rules promulgated pursuant thereto.

(b) Those factors which shall be considered relevant as to whether a facility meets the definition of a health care facility or service shall include:

1. The types of health care service and facilities, and changes thereto, which are required to obtain certificate of need approval by the provisions of this subchapter;

2. The type of health care service delivered or to be delivered, its impact on existing health care facilities and providers and its potential effect on the health care delivery system;

3. The degree of complexity in terms of medical technology, equipment, and the medical, paramedical and administrative staffing required to provide the health care service; and

4. Any other factors specific to the unique circumstances of an individual applicant.

(c) When a determination is made that a health care service/health care facility is deemed to require certificate of need review, the person(s) involved shall be so notified by the Commissioner. The Commissioner's decision shall be a final agency decision.

8:33-2.3 Reserved

8:33-2.4 Reserved

SUBCHAPTER 3. TYPES OF CERTIFICATE OF NEED APPLICATIONS

8:33-3.1 Initiation of health care service

Establishment of any of the specified standard categories of health care services as referenced in N.J.S.A. 26:2H-1 et seq., as amended and/or as identified in the chapter Appendix, Exhibit 1, incorporated herein by reference, or the modification, replacement or expansion of any health care service or facility, regardless of the amount of capital or operating expenditures requires a certificate of need except as exempted by P.L. 1992, c.160, as amended by P.L. 1998, c. 43 or otherwise exempted pursuant to this chapter. The certificate of need application shall be subject to the full review or direct review process, except as provided for at N.J.A.C. 8:33-5.1(a).

8:33-3.2 Termination/discontinuance of service or facility and/or reduction of licensed bed capacity

(a) Any health care facility which has closed or substantially ceased operation of any of its beds, facilities or services which require a certificate of need to be initiated, for any consecutive two-year period, shall be required to obtain a certificate of need before reopening such beds, facilities, or services.

(b) Voluntary closure of a facility or discontinuance of all of its services does not require a certificate of need, except that the closure of a general hospital requires a certificate of need and shall follow the full review process. Applications for the closure of a general hospital shall be accepted on the first business day of any month. Where a certificate of need is not required pursuant to this section, written notification shall be filed with the Department's Certificate of Need and Acute Care Licensure Program, 30 days prior to the proposed closure of a facility or discontinuance of all of its services. Full compliance with all applicable Department requirements contained in this chapter and in service-specific chapters for closure/discontinuance shall be required.

(c) Discontinuance of a component service of a health care facility or satellite emergency department shall not require a certificate of need where the discontinuance will not result in problems of access to populations historically served and is not a service which is required to be a component of an inpatient health care facility. In these instances, the licensed entity shall notify the Department's Certificate of Need and Acute Care Licensure Program in writing 60 days prior to discontinuance of the service. Such notice shall include a rationale of why the licensed entity anticipates that discontinuance will not result in problems of access, including access to women's reproductive health services, where contextually applicable. The Department will notify the provider whether the proposed discontinuance requires a certificate of need. If a certificate of need is required, the certificate of need application shall follow the expedited review process set forth at N.J.A.C. 8:33-4.1(c). The provider shall not discontinue the service until the Department provides notice that no certificate of need is required or that a certificate of need is approved, as applicable.

8:33-3.3 Transfer of a health care service/facility

(a) A certificate of need is required for a transfer of ownership of the following:

1. An entire general hospital. Applications for such shall follow the full review process set forth at N.J.A.C. 8:33-4.1(a), and shall be accepted on the first business day of any month; and

2. A transfer that will result in a new Medicare provider number for the hospitals involved in the transfer. Applications for such shall follow the full review process set forth at N.J.A.C. 8:33-4.1(a).

(b) A certificate of need is not required for transfer of ownership of all other operating health care facilities, beds, services or equipment not specified in (a) above. Where a certificate of need is not required pursuant to this section, application for a license on forms prescribed by the Department shall be filed with the Department's Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable, in accordance with this chapter and the Department's licensing rules.

(c) If a transfer of ownership occurs without a required certificate of need, then a daily penalty as established in the service-specific licensing rules promulgated by the Department may be assessed on the "new" owner and/or operator from the date of the unapproved transfer to the date the Department grants formal ownership approval to the "new" owner and/or operator.

(d) In the review of a transfer of ownership application, the prospective owner(s)/operator(s) shall be evaluated by the Department on the basis of character and competence and track record with regard to past and current compliance with state licensure, applicable Federal and certificate of need requirements, as specified in N.J.A.C. 8:33-4.9 and 4.10.

(e) A prospective owner approved for any transfer of ownership shall be subject to the same Department certificate of need, licensure, and reimbursement requirements as the current owner, including continuing compliance with any applicable certificate of need conditions, except that the Commissioner may amend the requirements to relate to changes in the health care system.

(f) These rules apply to ownership by any individual, partnership, limited liability partnership, corporation, limited liability corporation, or other entity in any entity which is the licensed operator of a facility or which owns the facility's real property. Except as otherwise provided in (h) below, a transfer of ownership which requires a certificate of need is defined as an acquisition or transfer which will increase or establish an ownership interest in a health care facility, as defined in N.J.A.C. 8:33-1.3, through purchase, lease, purchase or lease option, gift, donation, exchange, or by any other means. Types of ownership interests to which these rules apply include, but are not limited to, the following:

1. Shares of stock or any other type of security private business corporation;

2. Partnership interests in a general or limited partnership;

3. Ownership of a proprietorship or any other entity which operates a health care facility; and

4. Holding title to real property which is used to operate health care facility, or having a leasehold interest in such real property.

(g) Applications for transfer of ownership shall specify each and every principal in the entity which is the prospective owner and shall account for 100 percent of the ownership of the facility, except that if the ownership and operation is a publicly held corporation, each and every principal who has a 10 percent or greater interest in the corporation shall be identified by name, home address and percentage of interest.

(h) The following types of changes by operating health care facilities shall not require certificate of need approval by the Department as transfers of ownership, but shall require prior written notice to the Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable, of any such sale and identification of ownership changes:

1. The purchase or sale of less than 10 percent of the outstanding stock (preferred or common) in a business corporation, except that any purchase of stock which results in an individual holding 10 percent or more of the corporation's outstanding stock when the individual previously held less than 10 percent of the stock shall require certificate of need approval;

2. The purchase or sale of limited partnership interests in a limited partnership, where a written limited partnership agreement prohibiting participation in management of the partnership by limited partners has been submitted to the Department. This exception shall not apply to general or managing partners or to any partner who participates in management;

3. A change in the membership of a nonprofit corporation, where the members are individuals or nonprofit corporations, and there is no purchase or sale of assets. In cases involving general hospitals, the facility shall provide notification documenting, to the satisfaction of the Commissioner, that the membership change does not diminish access to previously provided community services, including, but not limited to women’s reproductive health services. If the Commissioner determines that there will be decreased access to existing community services, a facility shall be required to file a certificate of need application. The application shall be subject to the expedited review process, as set forth at N.J.A.C. 8:33-5.2(c);

4. A change in ownership which does not involve acquisition of an ownership interest by a new principal; that is, the change involves only the percentage owned by the principals in the entity which is the licensed operator of the facility or involves withdrawal of one or more principals from ownership in the facility;

5. The death of a principal in a health care facility, which shall be reported to the Department's Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable, together with the identity of the heir(s) to the ownership interest of the deceased principal. If the heir(s) intends to retain the ownership

interest, the heir(s) shall be subject to investigation of licensure track record. Otherwise, the Department may accept an application to transfer the heir's ownership interest. Any other transfer of ownership which occurs by operation of law shall be reported in the same manner; and

6. A transfer, which involves a change in the controlling legal entity, but not in individuals with ownership interests, including, but not limited to:

i. A change in the type of organizational entity owning the facility only, with no change in the principals with ownership interests (for example, a change from a corporation to a partnership or vice versa);

ii. The merger or consolidation of a corporation with or into its wholly-owned subsidiary;

iii. The merger or consolidation of a corporation with or into a corporation with identical common ownership;

iv. A transfer of assets to an entity with identical common ownership;

v. A transfer of assets to a wholly-owned subsidiary corporation;

vi. A transfer of assets from a wholly-owned subsidiary corporation to its parent;

vii. A transfer of stock to a wholly-owned subsidiary; or,

vii. A transfer of stock to an entity with identical common ownership.

(i) Any person or entity which loans money for the construction of, capital improvements to, or operation of a health care facility may hold as security therefore such liens, mortgages, pledges, and other encumbrances on the assets, real property, or stock or other ownership interests in the health care facility as provided in any loan or security agreement with the borrower and to the fullest extent permitted by law. If a lender acquires an interest in all of the assets or ownership of a health care facility upon foreclosure of any such security interest upon default, such lender shall promptly make application for a certificate of need in accordance with this subchapter and shall be permitted to operate the facility pending review and approval of said application provided that such lender shall demonstrate to the satisfaction of the Department that the health, safety and welfare of the patients will be maintained in the interim.

(j) Except as otherwise provided in (k) below, the transfer of unimplemented certificates of need is prohibited. Proceeding with any such transfer shall nullify the certificate of need and preclude licensure as a health care facility.

(k) At the discretion of the Department, an exception to the prohibition, at (j) above, on the sale of certificates of need prior to licensure may be permitted and the certificate of need process for transfer of ownership may be allowed to proceed on an unimplemented certificate of need if the types of changes set forth at (h)l through 6 above apply. Applicants for transfers of unimplemented certificates of need shall demonstrate in the application that the transfer will not adversely affect the financial feasibility of the project.

(l) If a lender or creditor acquires an ownership interest in the physical assets of an unimplemented certificate of need project through foreclosure on a mortgage, lien, or other security interest, the certificate of need may be automatically nullified, based on the provisions

of this chapter, except that the Commissioner may consider the transfer of the certificate of need to the new owner of the site where the certificate of need approved project has been substantially completed as determined by the Commissioner, and where the Commissioner finds that the completion of the project would be in the best interest of the population to be served and the entity acquiring ownership interest complies with track record requirements set forth at N.J.A.C. 8:33-4.10(d).

(m) If the facility being transferred has any partially implemented or unimplemented certificate of need approvals, an application for a license to own and/or operate the facility by the new owner will not be accepted by the Licensing Program unless the current owner/operator surrenders to the Department the unimplemented certificate of need approvals. The Commissioner may waive this requirement, based on a determination that the project has been substantially completed and that completion of the project is in the public interest, consistent with the principles set forth at N.J.A.C. 8:33-1.2.

8:33-3.4 Changes in licensed beds and/or services

(a) The following criteria apply to changes in licensed beds and/or services:

1. Any increase in the number of licensed beds by licensure and/or health planning category requires a certificate of need unless the bed type is specifically exempted from the certificate of need requirement pursuant to P.L. 1992, c. 160, as amended by P.L. 1998, c. 43, section 19 (N.J.S.A. 26:2H-7a), or otherwise exempted pursuant to this chapter. The certificate of need application shall be subject to the full review process, except as provided for at N.J.A.C. 8:33-5.1(a).

2. Any decrease in the number of licensed beds by licensure and/or health planning category shall not require a certificate of need. Conversions of licensed beds to other uses shall be treated as increases in the number of beds by licensure or health planning category and the provisions of (a)1 above shall apply.

3. For services for which there is no specific licensed bed complement, relocation is not permitted, unless the service is otherwise exempt from the certificate of need requirement in accordance with those rules. For services for which there is a specific licensed bed complement, the relocation of a portion of a facility's licensed beds or the entire service from one licensed facility (sending facility) to another (receiving facility) located within the same planning region requires a certificate of need and shall follow the expedited review process, unless the beds or service at issue are otherwise exempt from the certificate of need requirement in accordance with these rules. The application shall be considered pursuant to the following criteria:

i. The relocation shall take place within the same planning region where the sending facility is located;

ii. The receiving facility shall already hold a license for the category of beds proposed for relocation. The Commissioner may, in the case of proposed bed relocations, waive this requirement when the receiving facility is the site of a general hospital proposed or approved

for closure in the previous 12 months, if the Commissioner makes a finding that such approval will not reduce quality of care associated with the beds;

iii. The relocation shall not have an adverse impact on the ability of the population currently being served in the sending facility's service area to access the same types of service or bed complement as those proposed for relocation;

iv. The relocation shall not reduce access by the medically underserved and shall address the criteria set forth at N.J.A.C. 8:33-4.10(a);

v. The relocation shall not have an adverse impact on quality of care at either the sending or receiving facility;

vi. All minimum and maximum bed/unit size requirements (for example, six bed pediatric units, 10 bed obstetrics units, 240 bed long-term care facilities) shall be maintained at both the sending and receiving facilities; and

vii. The relocation shall not violate a condition of a prior certificate of need approved for the establishment of the beds or services, unless the applicant presents evidence of substantial changes since imposition of the condition and the Commissioner makes a finding that the evidence warrants removal or modification of the condition.

4. The relocation of a portion of a health care facility's licensed beds or an entire service, whether it has a bed-related component or not, from one licensed facility to another outside the same planning region shall not be permitted.

8:33-3.5 Buildings

(a) The following criteria apply to buildings:

1. Regardless of cost, a certificate of need is required for the establishment of a new health care facility unless the facility type is specifically exempted from the certificate of need requirement pursuant to section 19 (N.J.S.A. 26:2H-7a)**,** as amended by P.L. 1998, c. 43, or otherwise exempted pursuant to this chapter. The certificate of need application shall be subject to the full review process, except as provided for at N.J.A.C. 8:33-5.1(a).

2. Replacement at the same site of an existing licensed health care facility that is subject to the certificate of need requirement shall be exempt from the certificate of need requirement, providing such replacement meets the following criteria:

i. The facility proposed for replacement is not licensed as a general hospital;

ii. The existing facility proposed for replacement is not adding beds or services within any licensure and/or health planning category that is subject to the certificate of need requirement to its total licensed bed or service complement not previously offered by the applicant at the existing facility already approved by the Department's Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable;

iii. All direct patient services in the existing facility shall cease operation once the replacement facility is licensed; and

iv. The replacement facility shall be located at the existing site**.**

3. The relocation of an entire licensed health care facility that is subject to the certificate of need requirement to a new site outside the same planning region as the existing facility site shall not be permitted.

4. The relocation of an entire licensed health care facility that is subject to the certificate of need requirement to a location within the same planning region requires a certificate of need and shall follow the expedited review process, unless the facility is otherwise exempt from the certificate of need requirement in accordance with these rules, subject to the provisions set forth at N.J.A.C. 8:33-3.4(a)3i through vii and as follows:

i. The facility proposed for replacement or relocation is not licensed as a general hospital;

ii. The existing facility proposed for relocation is not adding beds or services within any licensure and/or health planning category that is subject to the certificate of need requirement to its total licensed bed or service complement at the proposed replacement facility; and

iii. All direct patient services in the existing facility shall cease operation once the replacement facility is licensed.

8:33-3.6 Reserved

8:33-3.7 Major moveable equipment

(a) Applications to initiate full service or low risk invasive adult cardiac diagnostic services will only be accepted by the Department in accordance with the eligibility and application review criteria set forth in N.J.A.C. 8:33E. All such applications will be subject to the expedited certificate of need review process set forth at N.J.A.C. 8:33-5.

(b) Addition of cardiac catheterization equipment by a general hospital licensed to provide full service invasive cardiac diagnostic services is exempt from the certificate of need requirement.

(c) Replacement of cardiac catheterization equipment is exempt from the certificate of need requirement.

(d) Health care equipment which involves new technology that is not identified in this chapter shall not be subject to certificate of need requirements, but shall meet the following requirements:

1. The new technology shall be directly related to an already licensed health care service for which the provider has obtained a certificate of need, if applicable, and is already licensed;

2. The provider shall provide the Commissioner with written notice of the intent to initiate the new technology at least 60 days prior to the date the provider will begin use of the technology;

3. The new technology shall have pre-market approval from the Federal Food and Drug Administration and meet all other applicable State and Federal legal and regulatory requirements, if any;

4. The provider shall use the new technology in accordance with guidelines approved by the Joint Commission on Accreditation of Health Care Organizations until such time as the Department may adopt licensing standards for the new technology. The provider shall comply with the Department's licensing standards for the new technology upon adoption of applicable standards; and

5. The provider shall agree to submit to the Department patient information and other data concerning use of new technology. The provider shall submit data, as specified by the Department until such time as the Department determines that further reporting is not required.

(f) Upon a finding by the Commissioner that the provider's use of new technology is not in compliance with the provisions set forth in (d)1 through 5 above, the Commissioner may suspend the use of same.

8:33-3.8 Minor moveable equipment

Regardless of capital cost, a certificate of need shall not be required for the acquisition, replacement, expansion or transfer by any person, including a physician, of minor moveable equipment.

8:33-3.9 Changes in cost/scope

(a) A change in cost of an approved certificate of need is exempt from certificate of need review subject to the following:

1. The applicant shall file a signed certification as to the final total project cost expended for the project at the time of application for license for the beds/service with the Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable;

2. Where the actual total project cost exceeds the certificate of need approved total project cost and is greater than $1,000,000, the applicant shall remit the additional certificate of need application fee due to the Certificate of Need and Acute Care Licensure Program. The required additional fee shall be 0.15 percent of the total project cost in excess of the certificate of need approved total project cost. Certified checks, cashiers' checks or money orders must be made payable to Treasurer, State of New Jersey.

3. The Department will not issue a license for the beds/service until the additional fee is remitted in full.

(b) The following criteria apply to a proposed change in location of an unimplemented certificate of need project:

1. A proposed change in location of the entire complement of beds and services approved in an unimplemented certificate of need project within the same county shall be exempt from the certificate of need review requirement, providing such change in the location meets the following criteria. A proposed change in location that is exempt from the certificate of need requirement requires the submission of a written proposal to the Certificate of Need and Acute Care Licensure Program addressing the following requirements. The applicant may not proceed with the change in location until written authorization is issued by the Department.

i. The change in location shall not have an adverse impact on the ability of the population to be served in the original application to access the beds or services proposed for relocation, as determined by the Department. A change in location which will have an adverse impact on the delivery of services to the population to be served in the original application, as determined by the Department, shall require a certificate of need review and follow the expedited review process, subject to the provisions set forth at N.J.A.C. 8:33-3.4(a)3.

ii. The change in location shall not violate a condition of approval of the unimplemented certificate of need. A change in location shall not be permitted where the unimplemented certificate of need project is subject to a condition of approval specific to the location of the project;

2. A proposed change in location of the entire complement of beds and services approved in an unimplemented certificate of need project outside the approved county but within the same planning region requires a certificate of need, and shall follow the expedited review process, subject to the provisions set forth at N.J.A.C. 8:33-3.4(a)3. Changes in location to a proposed site outside the same applicable planning region are not permitted.

3. A proposed change to more than one location within the same county of an unimplemented certificate of need approved for the establishment of beds shall be exempt from the certificate of need requirement, provided such change in the location meets the following criteria. A proposed change in location that is exempt from the certificate of need requirement requires the submission of a written proposal to the Certificate of Need and Acute Care Licensure Program addressing the following requirements. The applicant may not proceed with the change in location until written authorization is issued by the Department.

i. The beds shall be relocated within the same county as stated in the original certificate of need application and approved by the Commissioner;

ii. The beds at each site shall be licensed to the identical operating entity identified as the applicant in the original certificate of need application;

iii. All minimum and maximum bed/unit size requirements, as set forth in these and applicable licensing rules, shall be maintained at each facility;

iv. The proposed change in location shall not have an adverse impact on the ability of the population proposed to be served in the original location to access the beds proposed for relocation;

v. The proposed change in location shall not violate a condition of approval of the unimplemented certificate of need. A proposed change in location shall not be permitted where the unimplemented certificate of need project is subject to a condition of approval specific to the location of the project; and

vi. Each facility shall comply with all applicable licensing requirements.

4. A proposed change to more than one location outside the county of an unimplemented certificate of need approved for the establishment of beds, but within the same applicable planning region shall follow the expedited review process, subject to the provisions set forth at N.J.A.C. 8:33-3.4(a)3. Changes in location to proposed sites outside the planning region are not permitted.

5. A proposed change to more than one location within the same county and outside the county of an unimplemented certificate of need approved for the establishment of beds, but within the same applicable planning region shall follow the process identified at (b)3 and 4 above.

(c) Any change in the total approved square footage to be renovated and/or constructed does not require a certificate of need.

(d) The following criteria shall apply to changes in beds, complement of major moveable equipment and array of services:

1. A certificate of need is not required for a change in scope to an unimplemented certificate of need which results in a reduction of beds, elimination of approved major moveable equipment or elimination of services providing the change does not violate a condition of certificate of need approval. In these instances, the applicant shall be required to provide notification in writing to the Department's Certificate of Need and Acute Care Licensure Program of the specific reductions in scope for approval by the Department prior to implementation. If the proposed reduction would result in a violation of a condition of approval, a certificate of need for change in scope shall be required and shall follow the expedited review process.

2. The Department shall not accept for processing the following changes in scope. Failure to implement the scope of the project as approved shall result in nullification of the unimplemented certificate of need and require the filing of a new certificate of need application in the next appropriate cycle.

i. Any increase in the number or category of approved beds that is subject to the certificate of need requirement, unless the increase is solely for the addition of assisted living or comprehensive personal care beds; or

ii. Addition/expansion of services approved within the application or any standard categories of health care services in Appendix Exhibit 1 that is subject to the certificate of need requirement.

(e) The following criteria apply to changes in service area, access or availability to the approved project, population served:

1. The Department shall not accept for processing the following changes in the scope of any unimplemented certificate of need. Failure to implement the scope of the project as approved shall result in nullification of the certificate of need and require the filing of a new certificate of need application in the next appropriate cycle.

i. Relocation of the proposed project outside the county for which it was originally approved**,** if the location was subject to a condition of certificate of need approval which prohibits relocation; or

ii. Change in the population served including percentage of Medicaid and medically indigent required to be served as a condition of certificate of need approval.

(f) Any modifications to the project as approved shall be reported to the Department's Certificate of Need and Acute Care Licensure Program in writing for review and approval prior to implementation.

8:33-3.10 Duration of an unimplemented certificate of need

(a) The following criteria apply to the duration of a certificate of need:

1. The certificate of need shall be valid for a period of five years from the date of approval, or as specifically identified in a call for certificate of need applications, in the applicable health planning regulation or other public notice issued by the Commissioner.

2. If an applicant requires an extension of time beyond the expiration date of the certificate of need, an application for extension of time shall be filed 60 days prior to the current expiration date. The application shall be subject to the expedited review process at N.J.A.C. 8:33-5.1. The application shall not be deemed complete unless the applicant provides documentation that the project's financing remains in place and is sufficient to cover cost increases, and that local zoning and/or local building approvals have already been obtained. The application shall document the reasons for delays and proposed detailed time frame identifying the remaining time needed for the project to be approved and/or licensed by the Department's Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable. Where the Commissioner determines that the approval should be extended for an additional time beyond its current expiration date, he or she shall assign an expiration date, based on the criteria contained in (a)3 below. Where the Commissioner denies the request for extension, the applicant may request a hearing pursuant to the Administrative Procedure Act, P.L. 1968, c. 410 (N.J.S.A 52:14B-1 et seq. and 52:14F-1 et seq.) and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1, in accordance with N.J.S.A. 26:2H-9. Requests for a hearing shall be made to the Department within 30 days of receipt of notification of the Commissioner's action. The Department shall arrange for a hearing within 60 days of receipt of a request, and after such hearing the Commissioner or his or her designee shall furnish the applicant with the hearing examiner's written recommendations and

reasons therefor. The Commissioner, within 30 days of receiving all appropriate hearing records, shall make his or her determination, which shall be a final agency decision.

3. If the project has not been licensed by the Department's Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable, within the original or, if applicable, extended time frame identified within this subchapter, the certificate of need shall automatically be deemed to be terminated.

8:33-3.11 Demonstration and research projects

(a) Projects which satisfy the definition of a research project, as specified at N.J.A.C. 8:33-1.3, shall be exempt from certificate of need requirements as long as they are conducted exclusively for the purposes of investigational studies and scientific research.

(b) At the conclusion of the research project, the health care services and equipment provided in the course of the research shall no longer have certificate of need exemption status. At that time, if the services and equipment used are to be continued such that they shall be provided to the general population or where billings for such services or equipment shall occur or reimbursement received, a certificate of need where applicable shall be obtained in accordance with the provisions of this chapter and all other applicable health planning rules.

(c) This subsection sets forth the requirements for an inner city cardiac satellite demonstration project:

1. The purpose of an inner city cardiac satellite demonstration project, as defined in N.J.A.C. 8:33-1.3, is to test the hypothesis that permitting a licensed inner city teaching hospital to provide invasive therapeutic cardiac services at a satellite hospital within the same hospital system shall maintain or improve the financial stability of the inner city hospital and promote the continued provision of the full range of services and programs which it provides. This project allows qualifying hospital systems to generate greater revenue for inner city hospitals by enabling them to provide invasive therapeutic cardiac services at a satellite hospital, the benefits of which shall then be credited to the inner city hospital, thereby enabling the inner city hospital to improve access to and the quality of invasive therapeutic cardiac services to medically underserved populations.

2. Inner city cardiac satellite demonstration projects shall obtain a CN pursuant to the expedited review process set forth in N.J.A.C. 8:33-5 and in response to a call issued by the Department. All activities of both the inner city hospital and the satellite hospital shall be governed by the rules concerning cardiac surgery centers, at N.J.A.C. 8:33E.

3. In order to implement the demonstration project gradually, the Department shall accept no more than two certificate of need applications, for cardiac satellite demonstration projects in any consecutive 24-month period, beginning on July 1, 1998. In addition to meeting the remaining criteria set forth in this subsection, only those applicants providing convincing evidence that the proposed project shall increase access to invasive therapeutic cardiac services

among minority and medically underserved populations through the increased revenue reasonably expected through implementation of the project, shall be accepted.

4. An inner city cardiac satellite demonstration project shall submit an application to the Department that, at a minimum, demonstrates that the proposed inner city cardiac satellite demonstration project satisfies the following criteria:

i. The inner city hospital shall be part of a multi hospital system and shall be a licensed teaching hospital that provides a comprehensive complement of invasive therapeutic cardiac services;

ii. Prior to the provision of the invasive therapeutic cardiac services at the satellite hospital, and on a periodic basis thereafter as determined by the Department, the inner city hospital and the satellite hospital shall each comply with all licensure criteria governing the provision of invasive therapeutic cardiac services, including those contained within N.J.A.C. 8:43G-7;

iii. Net revenues generated from the provision of invasive therapeutic cardiac services at the satellite hospital shall be utilized to benefit the inner city hospital. Upon application, the inner city hospital shall provide to the Department a report prepared by an independent accounting firm approved by the Department. The report shall provide an estimated projection of the amount of net revenues and expenses expected as a result of the implementation of an inner city cardiac satellite demonstration project, together with the methodology utilized to calculate the reported net revenues. The methodology shall comport with fair market valuation of all costs and revenues. The report shall further set forth a plan demonstrating the manner in which reported net revenues shall be used to increase access to and the quality of invasive therapeutic cardiac services at the inner city hospital and to promote, generally, the financial stability of the inner city hospital and the continued provision of the full range of services and programs which it provides. Upon the conclusion of the first calendar year of operation of the inner city cardiac satellite demonstration project, and each year of operation thereafter, the inner city hospital shall provide to the Department an accounting, in a standardized format to be determined by the Department, containing the net revenues that have been utilized to benefit the inner city hospitals. In addition, a complete financial report from the satellite hospital shall be submitted to the Department, including all expenses and other financial information related to the invasive therapeutic cardiac center, and the services it provides. This report shall be submitted to the Department within 60 days after the close of each calendar year;

iv. The provision of invasive therapeutic cardiac services at a satellite hospital in accordance with this subsection shall not result in a diminution of the volume or quality of services at the inner city hospital, as compared to the volume and quality of services prior to the initiation of the demonstration project. Volume shall not decrease 20 percent or more below the previous level, and the quality shall not decrease, as measured by risk-adjusted mortality rates, compliance with nationally recognized quality improvement initiatives and other measures as determined by the Department on a case-by-case basis, depending upon the facts and circumstances. Upon application, the inner city hospital shall submit a plan that demonstrates how the volume and quality of the invasive therapeutic cardiac services at the inner city hospital will be maintained. Notwithstanding the foregoing, the inner city hospital shall satisfy the regulatory requirements set forth at N.J.A.C. 8:33E-2.3 that are applicable to invasive therapeutic cardiac procedures, governing volume and quality of services. If the Department determines that

the volume at the inner city hospital has decreased by 20 percent or more, or the quality is lower to a degree, for a consecutive 12-month period, the Department shall have the authority to rescind the satellite hospital's license to operate its invasive therapeutic cardiac services, upon notice to the inner city hospital and a six-month period to cure the deficiencies. The Department's determination to rescind the inner city hospital's license hereunder shall be final;

v. The provision of invasive therapeutic cardiac services at the satellite hospital shall be subject to the governance of the inner city hospital and operated in accordance with the policies, procedures, and protocols of the inner city hospital which shall hold the license;

vi. Every inner city cardiac satellite demonstration project shall record and maintain data on the operation of the project, the patients served, the outreach to minority and indigent communities, and other information requested of each project by the Department. Such data shall be reported in a standardized format determined by the Department, and provided to the Department on a quarterly basis within 30 days after the close of each quarter;

vii. The inner city hospital shall ensure the provision of invasive therapeutic cardiac services at both the satellite hospital and the inner city hospital and shall assure that both hospitals comply and continue to comply with all applicable licensure rules.

5. All facilities seeking to initiate an inner city cardiac satellite demonstration project pursuant to an approved certificate of need issued in accordance with the demonstration criteria described in this subchapter shall be initially licensed on an annual basis, in accordance with the provisions of N.J.A.C. 8:43G.

6. Licenses for inner city cardiac satellite demonstration project facilities may be renewed on an annual basis only upon a demonstration by the license holder to the satisfaction of the Commissioner, of full compliance with all applicable standards and criteria of this chapter; N.J.A.C. 8:43B; N.J.A.C. 8:33; N.J.S.A. 26:2H-1 et seq.; any applicable Federal law; and any additional conditions imposed upon the license holder in the original certificate of need approval.

7. These requirements for licensure shall be in addition to and not in limitation of any other applicable authorities not specifically mentioned herein and from which the facility in question has not been specifically exempted by law.

(d) The Commissioner shall accept certificate of need applications for bloodless surgery demonstration projects in accordance with the provisions of the expedited review process set forth at N.J.A.C. 8:33-5.1(a) following a call for applications.

1. The Commissioner shall approve, in writing, no more than two certificate of need applications for bloodless surgery demonstration projects in any consecutive 24-month period, beginning on August 16, 1999.

2. The Commissioner shall approve each bloodless surgical demonstration project for a period of no more than 30 months from the date of notice of the written approval, but the Commissioner, in his or her discretion, may extend the date of termination of a demonstration project upon written request made by the hospital approved for the bloodless surgical demonstration project, and the extent that the utilization, staffing, outcome, policy and procedure criteria of this rule have been achieved during the course of the demonstration period.

3. An applicant for a bloodless surgery demonstration project shall:

i. Be a general hospital meeting the requirements set forth at N.J.A.C. 8:33E and 8:43G; and

ii. Have an existing invasive cardiac diagnostic service that has been in compliance with the minimum annual utilization requirements at N.J.A.C. 8:33E-1.4(b)l and the cardiac licensing requirements at N.J.A.C. 8:43G-7 for at least the three year period prior to the date of submission of the application for the bloodless surgery demonstration project.

4. A general hospital proposing to engage in a bloodless surgery demonstration project shall submit an application to the Department demonstrating the following:

i. That the applicant's bloodless surgery demonstration program shall serve a minimum of 100 patients per year in which each procedure, if performed conventionally, would result in a blood loss of greater than or equal to 1,000 cubic centimeters;

ii. That the applicant shall have qualified staff and staffing levels for the bloodless surgery demonstration project at all times that shall promote safety, including a bloodless surgery program coordinator who shall be a graduate of an accredited school of nursing and hold a current license to practice nursing care in New Jersey, and who shall be responsible for administration of:

(1) Patient care activities;
(2) Compilation of statistical information;
(3) Marketing activities designed to promote patient access;
(4) Physician referrals;
(5) Program staffing;
(6) Maintenance of policies and procedures; and
(7) Consultation services;

iii. That the applicant's physical plant and equipment standards for the bloodless surgery demonstration project shall result in the highest level of successful bloodless surgical outcomes;

iv. The service area for the provision of the bloodless surgery demonstration project;

v. That the applicant has developed and shall implement policies and procedures for the daily operation of the bloodless surgery demonstration project addressing, at a minimum:

(1) Hospital administration and governance;
(2) Patient services;
(3) Quality improvement;
(4) Patient health care needs;
(5) Safety and infection control;
(6) Comfort and pain management;
(7) Skin integrity;
(8) Psychosocial and spiritual health;
(9) Patient and family education;

(10) Discharge planning;
(11) Technical aspects of care; and,

vi. That the applicant's bloodless surgery demonstration program will perform, at a minimum, 50 percent of its annual open heart surgery cases in accordance with the definition of "bloodless surgery" at N.J.A.C. 9:33-1.3.

5. A general hospital approved for a bloodless surgical demonstration project shall submit quarterly evaluation reports to the Department for the duration of the demonstration project, with a final evaluation report immediately following the completion of the demonstration project, unless the Commissioner determines and notifies the hospital in writing that the hospital shall report more or less frequently than quarterly.

i. Each evaluation report shall include documentation of the number of bloodless surgical procedures performed by type of surgery, and success rates in terms of both morbidity and mortality.
ii. Each report shall be accompanied by supporting data.

6. The standards and conditions set forth in the Commissioner's notice of approval of a bloodless surgical demonstration project shall be the applicable licensure standards for that demonstration project until the completion of the demonstration project, but shall be in addition to, not in lieu of, the general surgery licensure standards set forth at N.J.A.C. 8:43G-34, the cardiac surgery licensure standards set forth at N.J.A.C. 8:43G-7 and other licensing standards applicable for the type of surgery performed.

i. In the event that the Commissioner shall extend the period of the demonstration project by written notice, the same standards and conditions set forth in the initial notice of approval shall continue to apply during the duration of the extension of the demonstration project.
ii. All facilities seeking to initiate bloodless surgery demonstration projects described in this subchapter shall document compliance with all applicable requirements for cardiac surgery services and invasive therapeutic cardiac services as set forth at N.J.A.C. 8:33E, including facility and physician annual volume standards, personnel and staffing requirements. Compliance with the applicable requirements as set forth at N.J.A.C. 8:33E-2.1 through 2.14 shall be maintained throughout the period of the demonstration project and thereafter as required.

7. All facilities seeking to initiate bloodless surgery demonstration projects described in this subchapter shall be initially licensed in accordance with the provisions of N.J.A.C. 8:43G except as specifically set forth below.

i. Initial licenses granted to bloodless surgery demonstration projects shall be valid for a period not to exceed 30 months from the month in which the facility initiates its bloodless surgery demonstration project.
ii. Following the expiration of the initial license, licenses for bloodless surgery demonstration projects may be renewed only upon demonstration by the license holder to the satisfaction of the Commissioner of full compliance with all applicable standards and criteria of

this chapter, N.J.A.C. 8:43G, N.J.S.A. 26:2H-1 et seq., any applicable Federal law, and any additional conditions imposed upon the license holder in the original certificate of need approval, and only in accordance with the following protocol:

(1) No earlier than the completion of the 24th month following the initiation of the bloodless surgery demonstration project under this program, and no later than the completion of the 26th month following the initiation of such services, all facilities seeking renewal of licenses issued pursuant to the demonstration program described in this subchapter shall submit to the Department, documentation of their full compliance with all standards and criteria referenced in (d)7ii above, specifically including, but not limited to, the independently audited and verified criteria specified in N.J.A.C. 8:33-3.11(d)4.

(A) Failure to submit all information/documentation required for consideration of renewal in the time and manner set forth in (d)7ii(l) above, shall, absent the express written consent of the Department, constitute a basis for denial of the request for license renewal.

(B) Following the completion of the 26th month after the initiation of services under the bloodless surgery demonstration project, documentation of compliance with the requirements of (d)7ii(l) above shall only be accepted for consideration at the express written request of the Department.

(2) Upon receipt of the documentation required for renewal as set forth in (d)7ii(l) above, the Department shall review and evaluate the documentation, shall communicate with the facility to clarify and/or supplement the documentation as it in its sole discretion deems appropriate, and shall, no later than the completion of the 30th month following the month in which the facility initiated services under the bloodless surgery demonstration project, communicate a decision to the facility as to whether the license to provide services approved under this bloodless surgery demonstration project will be renewed.

(3) Facilities not receiving an express written notification of the renewal of their license authorized under the bloodless surgery demonstration project described in this subchapter in accordance with (d)7ii(2) above, shall cease all such services that were initiated as a result of the bloodless demonstration project as of the completion of the 30th month following the month in which such services were initiated and make medically appropriate referrals for all patients.

8. Notwithstanding (d)6 and 7 above, within 180 days following the promulgation of rules by the Department, in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., specific to standards for bloodless surgical programs and procedures, any conditions and standards set forth in a notice of approval of a bloodless surgical demonstration project that is less stringent than, or otherwise in conflict with, the standards promulgated by the Department shall be superseded by the rules.

i. In order to maintain approval of a bloodless surgical demonstration project, each general hospital with a bloodless surgical demonstration project shall submit documentation no later than 180 days following the effective date of such rules demonstrating that its bloodless

surgical demonstration project is in compliance with the new or additional standards set forth by the Department.

ii. A hospital that fails to submit documentation of its compliance with the new standards, or that otherwise fails to comply with the new or additional standards shall cease its bloodless surgical demonstration project within 30 days following the date of written notice from the Commissioner of the general hospital's failure to comply, except with respect to follow-up care and discharge planning for current patients participating in the bloodless surgical demonstration projects, and shall provide all necessary assistance to physicians and their patients in locating another hospital with an approved bloodless surgical program.

(e) The Commissioner may issue a call for demonstrations, not specifically identified in this section.

1. Such call will be activated upon public notice by the Commissioner inviting certificate of need applications for the specific service and published in the New Jersey Register no less than 45 days prior to the date the application is required to be filed.

2. Unless otherwise specified in these and other applicable rules, each demonstration application shall include the following:

i. Documentation of exactly what is proposed to be demonstrated;

ii. Patient care policies used as part of the demonstration, including criteria for inclusion/exclusion in the demonstration;

iii. Proposed staff and staff qualifications for the demonstration;

iv. Written documentation that otherwise eligible patients will be accepted into the demonstration regardless of ability to pay;

v. Documentation of what data will be collected to evaluate the demonstration project; and

vi. Written assurances that all data collected to evaluate the demonstration project shall be reported to the Department in accordance with requirements specified by the Department.

3. In the case of a demonstration that involves the addition of new beds or services otherwise subject to certificate of need, the applications shall be subject to review by the State Health Planning Board.

4. All demonstrations shall be approved for a period not to exceed two years unless otherwise specified in the call notice.

5. Approved demonstrations shall receive licensure approval from the Department to operate the service for the time period specified in the call notice plus the evaluation period specified by the Department in its approval letter, provided all applicable licensure standards are met.

i. All applicants for demonstrations shall be notified in writing by the Department as to whether they shall be permitted continued operation of the service that is the subject of the demonstration within 60 days of the expiration date of the demonstration license;

ii. Where the Department denies continuance of the demonstration project past the originally approved deadline, as set forth in (e) 4 above, the demonstration project shall cease operating not later than 30 days after receipt of the written denial notice by the Department. Operators of denied demonstration projects shall have the right to appeal the Department's denial. A Notice of Appeal shall be sent to the Department within 30 days of receipt of the Department's denial notice. The appeal process shall comply with the requirements set forth in the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

6. All applicants, through a resolution of its Board of Directors, shall acknowledge and accept the standards and criteria set forth for the demonstration as conditions of approval and agree to be bound thereto.

SUBCHAPTER 4. THE REVIEW PROCESS

8:33-4.1 Review cycles and submission dates

(a) The full review process involves the review of a certificate of need application by the State Health Planning Board, as well as the Department. The Commissioner shall publish in the New Jersey Register in February of each year an anticipated schedule for receipt of certificate of need applications subject to full review procedures for a two-year period, including the current calendar year. The Commissioner may announce additional or special calls for certificate of need applications beyond those identified in the yearly notice or may delete announced calls from the yearly notice. Changes to the published schedule shall be published in the New Jersey Register. Wherever practical, the Commissioner shall provide notice in accordance with this section to allow for a minimum of 90 days between the date of publication of the Commissioner's notice inviting certificate of need applications and the date for submission of applications in response to the notice(s). The notice shall identify the needed service(s), proposed geographic area(s) to be served, the date the application is due, and the date the application is deemed complete for processing. The State Health Planning Board shall forward recommendations to the Commissioner within 90 days after the application is deemed complete for processing unless a fair hearing is requested by an applicant in accordance with the procedures identified at N.J.A.C. 8:33-4.14. For batches with fewer than 20 applications, a final agency decision will be rendered by the Commissioner no later than 120 days after receipt of recommendations from the State Health Planning Board or a decision from the Office of Administrative Law, as applicable. For batches with 20 or more applications, a final agency decision will be rendered by the Commissioner no later than 180 days after receipt of recommendations from the State Health Planning Board or a decision from the Office of Administrative Law, as applicable.

1. The full review process for non-batched applications shall include 12 review cycles. The beginning of each cycle shall be the first business day of each month.

2. The full review process for batched applications shall be in accordance with the following schedule, except that if the first of the month the application is due falls on a Saturday, Sunday, or State holiday, the application shall be filed the first business day of the month in which the application is due:

Category	Deadline for Submission
Long-term care, specialized ventilator	1/2/03 and annually thereafter
Long-term care, specialized behavior modification	1/2/03 "
Long-term care, pediatric	1/2/03 "
Maternal and child health	1/2/03 "
Pediatric intensive care	9/1/02 "
Psychiatric beds	2/1/03 and every two years thereafter
Rehabilitation beds	3/1/03 "
Children's hospitals	4/1/04 and every three years thereafter

Transplantation	4/1/04	"
Mobile intensive care unit	6/1/04	"
Trauma	6/1/04	"
Long-term care, general	7/1/04	"
Home health	7/1/04	"
Burn center, program, unit	4/1/06 and every five years thereafter	
New general hospitals	4/1/06	"

3. Acceptance of batched applications submitted in accordance with the schedule in (a)2 above does not constitute a finding by the Department of need for the additional beds or services proposed in the application(s).

4. For services with longer than annual submission schedules, the Commissioner may announce special calls for receipt of certificate of need batched applications upon making a finding of extraordinary circumstances that warrant such a call prior to the next scheduled submission date.

5. The Department shall review the schedule in (a)2 above for adequacy at least every five years.

6. New cardiac surgery services shall follow the procedures specified at N.J.A.C. 8:33E.

(b) The expedited review process involves review of a certificate of need application by the Department. It does not include a review by the State Health Planning Board. The expedited review process will include 12 review cycles. The beginning of each cycle shall be the first business day of each month and a decision the Commissioner shall render shall be rendered by the Commissioner no later than 90 days thereafter, unless otherwise specified by rule or notice.

(c) The Department shall conduct an annual review of the certificate of need application and review process to determine timeliness in processing certificate of need applications. Failure by the Department to process at least 90 percent of certificate of need applications filed within the year within the timeframes stated herein shall result in immediate corrective action.

8:33-4.2 Development of applications

(a) Application for a certificate of need shall be made to the Department, in accordance with the requirements of this chapter, and shall be in such form and contain such information as the Department may prescribe.

(b) Before filing an application, applicants are encouraged to contact the Department to examine the relationship of the proposed project to the applicable plans, guidelines, and criteria.

8:33-4.3 Submission of applications

(a) Thirty-five copies of the application shall be submitted to:

Certificate of Need and Acute Care Licensure Program
New Jersey State Department of Health and Senior Services
PO Box 360, Room 403
John Fitch Plaza
Trenton, New Jersey 08625-0360
(609) 292-6552**,** or 292-7228

(b) Below is the schedule of fees, based on total project costs, required when submitting any application for a certificate of need for the expedited, direct, or full review process. Fees shall be paid in full at the time applications are filed. Failure to pay the appropriate application filing fee in full shall cause the application not to be accepted for processing. Certified checks, cashiers' checks or money orders must be made payable to Treasurer, State of New Jersey. No cash or personal checks will be accepted. The certificate of need application fee shall be non-returnable, except that, if an application is submitted in the incorrect batch, is unresponsive to the notice issued by the Commissioner or inappropriately requests expedited review, it may be declared not acceptable for processing by the Department, in which case the filing fee will be returned.

1. Establishment of a facility or service; Change in the capacity of an existing facility or service; Acquisition of major moveable equipment:

Total Project Cost (TPC)	Fee Required
$1,000,000 or less	$5,000
Greater than $1,000,000	$5,000 + 0.15% of TPC

2. Change in scope	$5,000
3. Change in cost for $1,000,000 or more	0.15% of additional project cost over $1,000,000
4. Extension of time	$5,000
5. Transfer of ownership	$5,000

8:33-4.4 Certificate of need filing requirements

(a) An applicant shall document in the application that he or she owns the site where the facility, service, or equipment will be located, or has an ownership or lease option for such site, which option is valid at least through the certificate of need processing period. A duly executed copy of the deed, option or lease agreement for the site shall be submitted with the certificate of need application and include identification of site, terms of agreement, date of execution and signature of all parties to the transaction. If the site is optioned or leased by the applicant, a copy of the deed held by the current owner shall be required at the time of filing.

(b) One hundred percent of the operation of the proposed facility, service or equipment shall be accounted for in the certificate of need application. Each and every principal involved in the proposal shall be identified by name, home address and percentage of interest, except that, if the operation is a publicly held corporation, each and every principal who has a 10 percent or greater interest in the corporation shall be identified by name, home address and percentage of interest. Where a listed principal has an operating interest in another health care facility, in this or any other state, identification of the principal(s), the health care facilities in which they have an operating interest, and the nature and amount of each interest shall be specified.

(c) If the applicant is a registered corporation, the name and address of the registered agent shall be identified in the application.

(d) The operator of the proposed facility, service, or equipment shall file and sign the application. In the case of transfer of ownership the proposed owner/operator is considered to be the applicant. However, both the current owner/operator and proposed owner/operator shall file and sign the application.

(e) If the applicant does not comply with all of the provisions in (a) through (e) above, the Department shall determine the application to be not acceptable for processing.

8:33-4.5 Review for completeness

(a) Only complete applications shall be processed. The Department alone shall make the determination of the completeness status of applications. The Department shall make a decision on the completeness status of an application after the applicant has been given the opportunity to supplement the application within a specified timeframe in response to specific questions by the Department. The Department shall then make a decision on the completeness of the application. The Department shall notify the applicant of its determination. Upon issuing a determination that an application is complete, copies thereof shall be referred by the Department to the State Health Planning Board for review. If an application has been determined to be incomplete, the Department shall notify the applicant in writing citing the specific deficiencies in the application. The filing fee shall not be returned. The applicant may file a new application in the next appropriate cycle with the appropriate information.

(b) An application which is unresponsive to the notice issued by the Commissioner, or inappropriately requests expedited review may be declared not acceptable for processing by the Department, based on the standards contained in the chapter and the applicable service-specific chapter. The Department shall notify the applicant of this decision and the filing fee shall be returned.

(b) Once an application has been submitted to the Department, no subsequent submission of information shall be accepted, unless specifically requested in writing by the Department. Questions from the State Health Planning Board shall be transmitted by the Department to the applicant. Responses to all questions shall be forwarded to the Department for dissemination to the State Health Planning Board.

8:33-4.6 Modification of applications

(a) Under no circumstances shall an application be modified or altered to change the number or category of inpatient beds, proposed services, equipment subject to a planning regulation, proposed operator, or change in site after the application submission deadline date. An applicant desiring to make such a modification or alteration shall be required to withdraw the application from the current cycle and submit a new application for the next cycle.

(b) Modifications not specified in (a) above, such as changes in square footage and change in cost, shall be permitted if such changes are in response to completeness questions from the Department and made prior to submission of the application to the review process.

8:33-4.7 Deferral of applications

(a) An applicant may request in writing a deferral for up to a total of six months for an individual application that is not competitive or comparatively reviewed. If the applicant fails to notify the Department in writing to reactivate the application within this time frame, a new application shall be required. An applicant may not defer an application submitted in a competitive or comparatively reviewed batch. If the applicant does not wish to proceed in the review process, the application shall be withdrawn.

(b) The State Health Planning Board, or the Department may defer an individual certificate of need application where the application is not competitive or comparatively reviewed with other applications. Where projects are competitive or comparatively reviewed, the State Health Planning Board, or the Department may defer the entire batch or only those projects which are competitive or comparatively reviewed. The basis for any deferral shall be specified in writing to the applicant. The period of deferral of an individual certificate of need application, all projects in a batch which are competitive or comparatively reviewed, or an entire batch of certificate of need applications may not exceed six months.

(c) An applicant may revise the deferred project costs to account for inflation and may be requested by the Department to submit additional updated information prior to reactivation of the application.

1. Reactivated applications with no changes or with only a change in cost may continue in the review process from the point of deferral.

2. Reactivated applications with any change in project scope shall be treated as a new application and shall follow the review process beginning with submission of the application to the Department, except that if the application is modified in a non-substantive way, that is, if the modification were proposed separately, it would either not require certificate of need review or would require only an expedited review, the application may continue from the point of deferral

(d) The Department shall not accept any requests for a deferral from the applicant once the State Health Planning Board has made its recommendation.

8:33-4.8 Withdrawal of applications

An applicant may submit a written request for withdrawal of its application prior to final action by the Commissioner. The certificate of need filing fee shall not be returned in the event of a withdrawn application. Once an action has been taken by the Commissioner, the application shall not be withdrawn.

8:33-4.9 General criteria for review

(a) No certificate of need shall be issued unless the action proposed in the application for such certificate is necessary to provide required health care in the area to be served, can be financially accomplished and licensed in accordance with applicable licensure regulations, will not have an adverse impact on access to health care services in the region or Statewide, and shall contribute to the orderly development of adequate and effective health care services. In making such determinations there shall be taken into consideration:

1. The availability of facilities or services which may serve as alternatives or substitutes;

2. The need for special equipment and services in the area;

3. The adequacy of financial resources and sources of present and future revenues;

4. The availability of sufficient manpower in the several professional disciplines; and

5. Other applicable requirements which are specified in any health planning rule adopted by the Department.

(b) It shall be the responsibility of the applicant to adequately and appropriately demonstrate that the proposed project meets the standards set forth in (a) above. It is not incumbent upon the reviewing agencies to demonstrate lack of need.

(c) No certificate of need shall be granted to any facility that, during the course of the application process, fails to provide or fails to contractually commit to provide services to medically undeserved populations residing or working in its service area as adjusted for indications of need. In addition, no certificate of need shall be granted to any facility that fails to comply with State and Federal laws regarding its obligation not to discriminate against low income persons, minorities, and disabled individuals.

8:33-4.10 Specific criteria for review

(a) Each applicant for a certificate of need shall show how the proposed project shall promote access to low income persons, racial and ethnic minorities, women, disabled persons, the elderly, and persons with HIV infections and other persons who are unable to obtain care. In determining the extent to which the proposed service promotes access and availability to the aforementioned populations, the applicant, where appropriate, shall address in writing the following:

1. The contribution of the proposed service in meeting the health related needs of members of medically underserved groups as may be identified in the applicant's service area;

2. The extent to which medically underserved populations currently use the applicant's service or similar services in comparison to the percentage of the population in the applicant's service area which is medically underserved, and the extent to which medically underserved populations are expected to use the proposed services if approved;

3. The performance of the applicant in meeting its obligation, if any, under any applicable State and Federal regulations requiring provision of uncompensated care, community services, or access by minorities and handicapped persons to programs receiving Federal financial assistance (including the existence of any civil rights access complaints against the applicant);

4. How and to what extent the applicant will provide services to the medically indigent, Medicare recipients, Medicaid recipients and members of medically underserved groups;

5. The extent to which the applicant offers a range of means by which its service (for example, outpatient services, admission by house staff, admission by personal physician) will be accessible and available to a person;

6. The amount of charity care, both free and below cost service, that will be provided by the applicant;

7. Access by public or private transportation to the proposed project**,** including applicant–sponsored transportation services;

8. As applicable, means of assuring effective communication between the staff of the proposed project and non-English speaking people and those with speech, hearing, or visual handicaps must be documented; and

9. Where applicable, the extent to which the project will eliminate architectural barriers to care for handicapped individuals.

(b) Each applicant for certificate of need shall demonstrate that the proposed project will maintain or enhance quality of care, can be financially accomplished and maintained, and licensed in accordance with applicable licensure regulations; how it shall address otherwise unmet needs in the planning region; that it shall not have an adverse impact on access to health care services; and that projected volume is reasonable. Evaluation of the applications shall include a review of:

1. Demographics of the area, particularly as related to the populations affected by the proposed project;

2. Economic status of the service area, particularly as related to special health service needs of the population; and future facility cash flow;

3. Physician and professional staffing issues;

4. Availability of similar services at other institutions in or near the service area;

5. Provider's historical and projected market shares;

6. The immediate and long term financial impact on the institution. This review shall assess:

i. Whether the method of financing identified is accurately calculated and economically feasible, and is the least cost method available;

ii. Impact of the proposed project on capital cost, operating cost, projected revenues, and charges for the year prior to the application and the two years following project completion;

iii. Impact of the proposed project on the provider's financial condition, as measured by financial statements, including balance sheets, income statements and cash-flow statements;

7. Whether the applicant has demonstrated the ability to obtain the necessary capital funds;

8. Each applicant for certificate of need shall demonstrate how the proposed project shall comply with applicable rules and regulations governing the construction, modernization or renovation of the project. The applicant shall address the following:

i. A cost estimate of the project stated in those dollars which would be needed to complete the project over the anticipated period of construction, assuming that construction was to begin at the time of the certificate of need submission; and

ii. A detailed description of the project including square footage, construction type, current and proposed use of areas proposed for renovations, anticipated construction related circumstances, impact of asbestos abatement, accounting of all displaced department services areas, relocations and vacated areas.

(c) The Commissioner may request any additional information deemed necessary to establish that the proposed project will not adversely affect the State's health care system.

(d) Each applicant for certificate of need shall demonstrate character and competence, quality of care, and an acceptable track record of past and current compliance with State licensure requirements, applicable Federal requirements, and State certificate of need requirements, including, but not limited to, the following:

1. The performance of the applicant in meeting its obligation under any previously approved certificate of need including full compliance with the cost and scope as approved, as well as all conditions of approval;

2. Applicants shall demonstrate the capacity to provide a quality of care which meets or surpasses the requirements contained in the applicable licensing standards for the facility. Evidence of the capacity to provide high quality care shall include (d)2i below and may, if applicable, also include (d)2ii through iv below:

i. A satisfactory record of compliance with licensure standards in existing health care facilities that are owned, operated, or managed, in whole or part, by the applicant. This may include reports issued by licensing agencies from other states, as well as from the Department. Applicants shall document their requests to licensing agencies in other states, where applicable, as well as the responses from those agencies. Applicants shall not be penalized for the failure of licensing agencies in other states to respond to their requests unless they failed to make the requests in a timely manner. In the event that an applicant is unable to obtain a written report from a licensing agency in another state, the applicant may submit, in lieu of the written report, an attestation that its compliance record in that state does not contain any violations of (d)3 through 5 below along with documentation of its efforts to obtain a written report;

ii. Narrative descriptions or listings within the application of services, staffing patterns, policies and protocols addressing delivery of nursing, medical, pharmacy, dietary, and other services affecting residents' quality of care;

iii. Documentation of compliance with the standards of accreditation of nationally recognized professional bodies; and

iv. Where applicable, a recommendation by the State Department of Human Services' Division of Medical Assistance and Health Services and Division of Mental Health Services regarding the quality of and access to services provided by the applicant to Medicaid patients and patients who have been discharged from State and county psychiatric hospitals;

3. The Department shall examine and evaluate the licensing track record of each applicant for the period beginning 12 months preceding submission of the application and extending to the date on which the Commissioner renders a decision with respect to the application, for the purpose of determining the capacity of an applicant to operate a health care facility in a safe and effective manner in accordance with State and Federal requirements. A certificate of need application may be denied where an applicant has not demonstrated such capacity, as evidenced by continuing violations or a pattern of violations of State licensure standards or Federal certification standards or by existence of a criminal conviction or a plea of guilty to a charge of fraud, patient or resident abuse or neglect, or crime of violence or moral turpitude. An application also may be denied where an applicant has violated any State licensing or Federal certification standards in connection with an inappropriate discharge or denial of admission. An applicant, for purposes of this rule, includes any person who was or is an owner or principal of a licensed health care facility, or who has managed, operated, or owned in whole or in part any health care facility, excluding individuals or entities who are limited partners with no managerial control or authority over the operation of the facility and who have an ownership interest of 10 percent or less in a corporation which is the applicant and who also do not serve as officers or directors of the applicant corporation;

4. A certificate of need application submitted by an applicant who was cited for any State licensing or Federal certification deficiency during the period identified in (d)3 above, which presented a serious risk to the life, safety, or quality of care of the facility's patients or residents, shall be denied, except in cases where the applicant has owned/operated the facility for less than 12 months and the deficiencies occurred during the tenure of the previous owner/operator. In any facility, the existence of a track record violation during the period identified in (d)3 above shall create a rebuttable presumption, which may be overcome as set forth below, that the applicant is unable to meet or surpass licensing standards of the State of New Jersey. Those applicants with track record violations which would result in denial of the application shall submit with their application any evidence tending to show that the track record violations do not presage operational difficulties and quality of care violations at the facility which is the subject of the application or in any other licensed long-term care category facility in New Jersey, which is operated or managed by the applicant. If, after review of the application and the evidence submitted to rebut a negative track record, the Commissioner denies the application, the applicant may request a hearing which will be held in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1. At the Commissioner's discretion, the hearing shall be conducted by the Commissioner or transferred to the Office of Administrative Law. The purpose of the hearing is to provide the applicant with the opportunity to present additional evidence in conjunction with evidence already included with the initial application, for the purpose of demonstrating the applicant's operational history and capacity to deliver quality of care to patients or residents which meets or surpasses licensing standards of the State of New Jersey to the satisfaction of the Commissioner or his or her designee. The conclusion of that process with either a decision by the Commissioner or the Commissioner's acceptance or denial of an initial decision by an administrative law judge shall constitute a final agency decision. A serious risk to life, safety, or quality of care of patients or residents includes, but is not limited to, any deficiency in State licensure or Federal certification requirements (42 C.F.R. 488.400 et seq.) resulting in:

i. An action by a State or Federal agency to ban, curtail or temporarily suspend admissions to a facility or to suspend or revoke a facility's license;

ii. A decertification, termination, or exclusion from Medicaid or Medicare participation, including denial of payment for new admissions, imposed by the Department or by the Health Care Financing Administration, as a result of noncompliance with Medicaid or Medicare conditions of participation.

5. In addition to the conditions specified at (d)4 above, an application for a long-term care category service, including, but not limited to, a long-term care facility, assisted living residence, assisted living program or comprehensive personal care home, shall be denied upon a finding that any long-term care facility or hospital-based subacute care unit in New Jersey operated or managed by the applicant has, within the 12 months preceding submission of the application and extending to the date on which the Commissioner renders a decision with respect to the application, been the subject of one or more of the following:

i. A citation of any deficiency posing immediate jeopardy at a pattern or widespread scope level, or any deficiency causing actual harm at a widespread scope level, as described at 42 C.F.R. 488;

ii. A determination that the provider is a "poor performer," on the basis of a finding of substandard quality of care or immediate jeopardy, as described at 42 C.F.R. 488, on the current survey and on a survey during one of the two preceding years. For the purposes of this subchapter, "substandard quality of care" means one or more deficiencies related to participation requirements under 42 C.F.R. 483.13, Resident behavior and facility practices, 42 C.F.R. 483.15, Quality of life, or 42 C.F.R. 483.25, Quality of care, which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm;

iii. A citation of a deficiency based on a finding of substandard quality of care in two different areas on the same survey. Such facilities will be afforded an opportunity to correct the deficiencies by a date specified in the Departmental notice accompanying the statement of deficiencies. If substantial compliance is achieved in all areas, the waiting period, as that term is defined in (d)10 above, shall terminate with the next standard survey of the facility, if that survey indicates substantial compliance. The Department shall conduct another full survey within approximately nine months of the date of the previous full survey during which the deficiencies were cited. If the deficiencies have not been corrected by the date specified in the Departmental notice accompanying the statement of deficiency, the 12-month waiting period shall commence on the date on which the deficiencies are corrected and compliance is achieved;

iv. A determination that the facility has failed to correct deficiencies which have been cited, and where this has resulted in a denial by the Health Care Financing Administration of payment for new admissions or a requirement by the Department to curtail admission.

6. The criteria for denial of an application specified in (d)4 and 5 above shall also result in denial of the application if the criteria are found to have been true of any number of out-of-State facilities operated or managed by the applicant, within the 12 months preceding submission of the application and extending to the date on which the Commissioner renders a decision with respect to the application and with respect to any service which is similar or related to the proposed service, constituting at least five percent of all facilities operated or managed by the applicant or five facilities in total, whichever is less.

7. In addition to the provisions of (d)l through 6 above, and notwithstanding any express or implied limitations contained therein, the Commissioner may deny any application where he or she determines that the actions of the applicant at any facility operated or managed by the applicant constitute a threat to the life, safety, or quality of care of the patients or residents. In exercising his or her discretion under this rule, the Commissioner shall consider the following:

i. The scope and severity of the threat;

ii. The frequency of occurrence;

iii. The presence or absence of attempts at remedial action by the applicant;

iv. The existence of any citations, penalties, warnings, or other enforcement actions by any governmental entity pertinent to the condition giving rise to the threat;

v. The similarity between the service within which the threat arose and the service which is the subject of the application; and

vi. Any other factor which the Commissioner deems to be relevant to assessment of risk presented to patients or residents.

8. For the purposes of this section, similarity or relatedness of any two services is determined by the inclusion of the two services together in one of the following categories:

i. The long-term care category, which includes but is not limited to long-term care facility, hospital-based subacute care unit, residential health care facility, alternate family care program, pediatric or adult day health care program, or assisted living provided through an assisted living residence, assisted living program or comprehensive personal care home.

ii. The general or special hospital category, which includes hospital services such as medical/surgical, pediatric, obstetric, cardiac, psychiatric, and intensive care/critical care, comprehensive rehabilitation, long term acute care, surgical services, magnetic resonance imaging and computerized tomography, extracorporeal shock wave lithotripsy, renal dialysis, positron emission tomography scanner, gamma knife, hyperbaric chamber, and birth centers.

iii. The ambulatory care and other category, which includes primary care, home health care, family planning, drug counseling, termination of pregnancy, birth centers, renal dialysis, magnetic resonance imaging, computerized axial tomography, extracorporeal shock wave lithotripsy, hyperbaric chamber, hospice, ambulatory surgery, and outpatient rehabilitation.

iv. The substance abuse treatment category, which includes residential alcohol treatment, residential drug treatment, and outpatient drug treatment.

9. In evaluating track records pursuant to (d)3 through 8 above, the Department may consider any evidence of noncompliance with applicable licensure requirements provided by an official state licensing agency in any state other than New Jersey, or any official records from any agency of the State of New Jersey indicating the applicant's noncompliance with the agency's licensure or certification requirements in a facility the applicant owned, operated, or managed in whole or in part.

10. Any person with a history of noncompliance with statutory or regulatory requirements which, as determined by the Department, threaten the life, safety or quality of care of patients shall be ineligible to file a certificate of need application until a waiting period of at least one year has elapsed, except as specified at (d)5iii above, during which time the person must have demonstrated a record of substantial compliance with licensing or regulatory standards. The one-year period shall be measured from the time of the last licensure or certification action indicating full compliance with regulatory standards.

11. No certificate of need application will be approved for any applicant with existing non-waiverable violations of licensure standards at the time of filing, or before final disposition of the application or for an applicant with a history of noncompliance with licensing, statutory or regulatory standards which, as determined by the Department, threaten the life, safety or quality of care of patients. An exception shall be made in the case of applications submitted for the purpose of correcting recognized major licensure deficiencies. An exception to this provision may also be granted for applications submitted for the closure of a general hospital.

8:33-4.11 Reserved

8:33-4.12 Reserved

8:33-4.13 Role of the State Health Planning Board

(a) The State Health Planning Board shall review applications for certificates of need subject to full review and make recommendations to the Commissioner in accordance with all applicable health planning regulations.

(b) A member of the State Health Planning Board shall not vote on any matter before the board concerning an individual or entity with which the member has, or within the last 12 months has had, any substantial ownership, employment, medical staff, fiduciary, contractual, creditor or consultative relationship. A member who has or has had such a relationship with an individual or entity involved in any matter before the board shall make a written disclosure of the relationship before any action is taken by the board with respect to the matter and shall make the relationship public in any meeting in which action on the matter is to be taken. Board members with a conflict of interest shall remove themselves from the table and shall not participate in the discussion of the relevant application(s).

(c) The State Health Planning Board shall furnish written decisions to the Commissioner which provide the explicit basis for any recommendations made by the Board on certificate of need applications. Such written decisions shall be forwarded to the Commissioner within 90 days after the application is deemed complete for processing unless the application has been deferred pursuant to N.J.A.C. 8:33-4.7 or because of the conduct of an administrative hearing regarding one of the batched applications. These written decisions may take the form of minutes of the State Health Planning Board.

8:33-4.14 Reserved

8:33-4.15 Procedures for Commissioner review

(a) The Commissioner may approve or deny an application for a certificate of need if the approval, or denial is consistent with all applicable health planning rules. The Commissioner shall issue a written decision on his or her determination of a certificate of need application which shall specify the reasons for approval or disapproval. The decision shall be sent to the applicant and to the State Health Planning Board, and shall be available to others upon request.

(b) Pursuant to N.J.S.A. 26:2H-9, if the Commissioner denies a certificate of need application, the applicant may request a hearing pursuant to the Administrative Procedure Act, P.L. 1968, c. 410 (N.J.S.A.52:14B-1 et seq. and 52:14F-1 et seq.) and the Uniform Administrative Procedure Rules N.J.A.C. 1:1.

(c) A request for a hearing shall be made to the Department within 30 days of receipt of notification of the Commissioner's decision. The hearing shall be conducted according to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1, and the record shall be limited to the documentary evidence presented to the reviewing agencies below. The Department shall arrange within 60 days of a request, for a hearing and after such hearing the Commissioner and or his or her designee shall furnish the applicant in writing the hearing examiner's recommendations and reasons therefor. The Commissioner within 30 days of receiving all appropriate hearing records shall make his or her determination, which shall be a final agency decision.

(d) After the commencement of a hearing pursuant to (c) above, and before a decision is made, there shall be no ex parte contacts between any person acting on behalf of the applicant or holder of a certificate of need, or any person opposed to the issuance of a certificate of need, and any person in the Department who exercises any responsibility for reviewing the application. Ex parte communication is defined as an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given. It shall not include requests for status reports on any matter or proceeding. Any communications made after commencement of the fair hearing that are placed in the record of the proceedings are made available to all parties are not ex parte and are not prohibited.

(e) The Department shall notify, upon their request, providers of health services and other persons subject to certificate of need requirements of the status of the review of certificate of need applications, findings made in the course of such review, and other information respecting such review after the certificate of need is deemed complete for processing.

(f) If the Department determines that the holder of an unimplemented certificate is not making a good faith effort to implement the project, the Commissioner may null and void the certificate. Prior to such a determination, the Department shall notify the holder of the certificate of its intent to initiate the nullification process. The holder of the Certificate shall have 30 days from the date of such notice to submit written documentation of the substantial progress which has been made, and which will continue, in implementing the Certificate. If, after the review of the documentation submitted, a notice of nullification is nevertheless issued, the holder may request a hearing pursuant to (c) above.

8:33-4.16 Conditions on approval/monitoring

(a) Conditions may be placed on certificate of need approval by the Commissioner if they relate to material presented in the application itself, are prescribed in State rules, relate to the criteria specified in N.J.A.C. 8:33-4.9 and 4.10 or promote the intent of the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq., as amended. The State Health Planning Board shall not recommend the inclusion of conditions in a certificate of need approval which are not consistent with the provisions of this subchapter.

(b) Any conditions placed on a certificate of need approval shall become part of the licensure requirements of the approved facility. Failure to comply with conditions of approval may result in licensure action by the Department and may constitute an adequate basis for denying

certificate of need applications by an applicant who is out of compliance with conditions on previous approvals. The applicant must contest any condition, if at all, within 30 days of receipt of notice. The applicant shall vacate his right to oppose said condition(s) if he fails to submit written notice that he contests any condition to the Department within this time. If the applicant contests a condition, the Commissioner shall suspend his or her approval of the certificate of need in order to consider the objection. Furthermore, the Commissioner has the right to nullify the approval of the certificate of need. The Commissioner may, at his or her discretion, consult with the State Health Planning Board to obtain its recommendation on the contested condition(s).

(c) When conditions are included in the Commissioner's approval letter, the applicant shall file a progress report on meeting such conditions with the Certificate of Need and Acute Care Licensure Program at least 12 months from the date of approval and annually for the first two years after project implementation and at any other time requested by the Department in writing. Failure to file such reports may be taken into consideration in the review of subsequent certificate of need applications, result in fines and penalties imposed through licensure action and/or result in the nullification of the unimplemented certificate of need.

(d) Where an applicant has failed to meet conditions of approval of previously approved certificates of need, it may form an adequate basis for the Department to bar the applicant from filing any subsequent certificate of need until the conditions in question are satisfied.

SUBCHAPTER 5. EXPEDITED REVIEW PROCESS

8:33-5.1 Statement of purpose

(a) The expedited review process shall be used for the following types of applications:

1. Establishment of a Statewide restricted admissions facility or increase in bed capacity of a Statewide restricted admissions facility;

2. Change in scope to an unimplemented certificate of need;

3. Establishment of or increase in the bed capacity of comprehensive personal care homes;

4. Establishment of or increase in the capacity of assisted living residences;

5. Establishment of assisted living programs;

6. Extension of time to an unimplemented certificate of need;

7. Conversion of existing, on-site, licensed residential health care beds to long-term care beds for long-term care facilities located in Newark, Jersey City, Paterson, Atlantic City, Camden, Elizabeth, Trenton, Irvington, East Orange or Union City that were issued a certificate of need between January 20, 1987 and September 8, 1992 pursuant to the methodology contained in then existing N.J.A.C. 8:33H-3.3(b)3 and were licensed on or before August 17, 1998;

8. Establishment of demonstration projects in accordance with applicable planning rules;

9. Establishment of a cardiac catheterization program or emergency or primary coronary angioplasty (PTCA) services with off-site cardiac surgery backup in accordance with N.J.A.C. 8:33E;

10. Establishment of a special hospital providing long term acute care services in accordance with the Department's licensure standards at N.J.A.C. 8:43G-38;

11. The relocation of a portion of a health care facility's licensed beds or an entire service from one licensed facility (sending facility) to another (receiving facility) located within the same planning region, unless the beds or service at issue are otherwise exempt from the certificate of need requirement;

12. The relocation of an entire licensed health care facility that is subject to the certificate of need requirement, except for general hospitals, within the same planning region.

(b) The expedited review process may also be used in lieu of the full review process, or in the following limited situations:

1. Emergency situations which demand rapid action; or

2. When the project has minimal impact on the health care system as a whole.

8:33-5.2 Process

(a) The expedited review process shall include 12 review cycles, where permitted by applicable planning regulations. The beginning of each cycle shall be the first business day of each month and a decision shall be rendered by the Commissioner no later than 90 days after the application has been accepted for processing.

(b) The determination of whether or not a project is accepted for processing under the expedited review process shall be made by the Department.

(c) Applications shall be reviewed to determine whether they are acceptable for processing. An original and nine copies of a signed and dated application, completely and accurately filled out shall be accompanied by the correct application fee and 10 copies of out-of-State track record reports. Applications not meeting these requirements shall not be accepted for processing. The Department shall notify the applicant of this decision and the filing fee shall be returned. The applicant may file a new application with the appropriate information in the next appropriate application submission cycle.

(d) Certificate of need applications subject to expedited review shall be reviewed in accordance with the requirements of this chapter, the Department's licensing rules and applicable health planning rules.

(e) Certificate of need application forms for expedited review may be obtained from the Department at the address listed below. Applicants should contact staff of the Certificate of Need and Acute Care Licensure Program before filing an application to be certain that they have a copy of the most recent version of the Department's application. Applications other than the Department's most recent version shall not be accepted for processing. An original and nine copies of the application shall be filed with:

Certificate of Need and Acute Care Licensure Program
New Jersey State Department of Health and Senior Services
John Fitch Plaza
PO Box 360, Room 403
Trenton, New Jersey 08625-0360
(609) 292-6552**,** or 292-7228

(f) Applications shall be reviewed by appropriate Department staff for the purpose of providing information to assist the Commissioner in making the final decision.

8:33-5.3 General requirements

(a) Minimum information required for all expedited review projects shall consist of:

1. Project description, including changes in beds, total project cost, services affected, equipment involved, source of funds, utilization statistics, both inpatient and outpatient, and justification for the proposed project;

2. The extent to which all residents of the area shall have access to services, particularly the medically underserved; and

3. Applicants for all services proposed for expedited review at N.J.A.C. 8:33-5.1(a), shall document that the following criteria shall be met:

i. Appropriate licensing and construction standards; and
ii. Licensure track record requirements (N.J.A.C. 8:33-4.10(d)); and

4. Additionally, cardiac catheterization program applicants shall comply with all relevant sections of N.J.A.C. 8:33E.

8:33-5.4 Specific requirements

(a) In addition to the requirements of N.J.A.C. 8:33-5.3, the following information shall be provided, as appropriate, for all expedited review projects:

1. For an applicant who applies under the expedited review process to convert existing, on-site, licensed residential health care beds to long-term care beds in accordance with N.J.A.C. 8:33-5.1(a)7:

i. A commitment that they will accept as a condition of certificate of need approval to maintain a minimum of 50 percent bed occupancy by direct Medicaid-eligible patients, of which 10 percent shall be discharged psychiatric patients from State and county hospitals. The aforesaid 50 percent and 10 percent bed minimums shall be calculated using the entire licensed bed capacity for the facility, shall be achieved no later than one year from approval, and shall be maintained at all times thereafter.

ii. A commitment that they will accept as a condition of certificate of need approval that the conversion of residential health care beds to long-term care beds shall occur within the city limits of the city identified in the application and the applicant shall not relocate all or any portion of the facility's total licensed long-term care capacity outside of the city limits.

2. For the relocation of a portion of a health care facility's licensed beds or an entire service from one licensed facility (sending facility) to another (receiving facility) located within the same planning region, applicants shall document compliance with the requirements set forth at N.J.A.C. 8:33-3.4(a)3.

3. For a proposed change in location of the entire complement of beds and services approved in an unimplemented certificate of need outside the approved county but within the same planning region, applicants shall document compliance with the requirements set forth at N.J.A.C. 8:33-3.9(b)2.

4. For a proposed change to more than one location outside the county of an unimplemented certificate of need approved for the establishment of beds, but within the same applicable planning region, applicants shall document compliance with the requirements set forth at N.J.A.C. 8:33-3.9(b)4.

SUBCHAPTER 6. CERTIFICATE OF NEED EXEMPTIONS

8:33-6.1 Statement of purpose

(a) In accordance with the provisions of the Health Care Reform Act, P.L. 1992, c.160 and the Certificate of Need Reform Act, P.L. 1998, c. 43 and N.J.S.A. 26:2H-7.2, the following specific health care services or projects are exempt from the certificate of need requirement:

1. Community-based primary care centers, as defined at N.J.A.C. 8:33-1.3, which provide preventive, diagnostic, treatment, management, and reassessment services exclusively on an outpatient basis to individuals with acute or chronic illnesses in a location and manner that is accessible to individuals;

2. Outpatient drug and alcohol services which include drug-free and methadone maintenance services and day treatment alcohol services;

3. Ambulance and invalid coach services, excluding mobile intensive care unit services.

4. Mental health services which are non-bed related outpatient services including outpatient centers, partial hospitalization programs and case management programs;

5. Residential health care facilities;

6. Transfer of ownership interest, except in the case of a general hospital;

7. Change of site for an unimplemented certificate of need within the same county;

8. Relocation or replacement of a health care facility within the same county, except for a general hospital;

9. Continuing care retirement communities authorized: pursuant to P.L. 1986, c.103 (N.J.S.A. 52:27D-330 et seq.) which contain a minimum of four independent living units for every one long-term care bed;

10. Magnetic resonance imaging;

11. Adult day health care facilities;

12. Pediatric day health care facilities;

13. Chronic or acute renal dialysis facilities**;**

14. Hospital-based medical detoxification for drugs and alcohol;

15. Capital improvements and renovations to health care facilities;

16. Addition of medical/surgical, adult intensive care, adult critical care beds in general hospitals;

17. Replacement of existing major moveable equipment;

18. Inpatient operating rooms;

19. Adult family care programs;

20. Hospital-based subacute care;

21. Ambulatory care facilities;

22. Comprehensive outpatient rehabilitation services;

23. Special child health clinics;

24. Addition of vehicles or hours of operation of a mobile intensive care unit;

25. Basic obstetric and pediatric services and birth centers, including addition of basic obstetric and pediatric beds in general hospitals;

26. Linear accelerators, including Cobalt 60 units;

27. New technology in accordance with the provisions set forth in N.J.A.C. 8:33-3.7(f);

28. Extracorporeal shock wave lithotripter;

29. Hyperbaric chamber;

30. Positron emission tomography;

31. Residential substance abuse treatment services;

32. Ambulatory surgical facilities;

33. Same day surgery operating rooms;

34. Long-term care facilities proposing to increase their total number of licensed long-term care beds by no more than 10 beds or 10 percent of their licensed long-term care capacity, whichever is less, within a period of five years pursuant to N.J.S.A. 26:2H-7.2;

35. Satellite emergency department;

36. A change in cost subject to the provisions set forth in N.J.A.C. 8:33-3.9(a);

37. Replacement at the same site of an existing licensed health care facility in accordance with the provisions set forth in N.J.A.C. 8:33-3.5(a)2; and

38. A proposed change in location of the entire complement of beds and services approved in an unimplemented certificate of need project within the same county in accordance with the provisions set forth in N.J.A.C. 8:33.3.9(b)1.

8:33-6.2 Process

(a) This section shall apply to projects which are exempt from the certificate of need requirement.

1. For continuing care retirement communities, a certificate of authority from the Department of Community Affairs for the operation of a continuing care retirement community shall be submitted to the Department prior to licensure of the long-term care beds.

2. If an applicant for licensure of a health care service or facility that is not subject to certificate of need review so requests, the Department shall provide the applicant with a pre-licensure consultation. The purpose of the consultation is to provide the applicant with information and guidance on rules, regulations, standards and procedures appropriate and applicable to the licensure process and licensure requirements. The Department shall conduct the consultation within 60 days of receipt of the request of the applicant.

APPENDIX

EXHIBIT 1
Health Care Services

A. Bed-related
   1. Pediatric intensive or critical care
   2. Comprehensive rehabilitation
   3. General long-term care
   4. Specialized long-term ventilator care
   5. Specialized long-term care for severe behavior management
   6. Pediatric long-term care
   7. Adult acute psychiatric (open and closed)
   8. Adult intermediate and special psychiatric
   9. Child and adolescent acute psychiatric
   10. Child and adolescent intermediate psychiatric
   11. Long term acute care

B. Non-bed-related
   1. Home health agency

C. Special Services
   1. Invasive cardiac diagnostic services
   2. Invasive therapeutic cardiac services
   3. Burn center, unit or program
   4. Organ transplant/organ procurement
   5. Perinatal services including neonatal intensive or intermediate services and maternal and child health consortia
   6. Mobile intensive care or advanced life support services
   7. Comprehensive personal care home
   8. Assisted living residence
   9. Bone marrow transplant/harvesting including stem cell
   10. Trauma services
   11. Specialty acute care children's hospitals
   12. Emergency medical service helicopters
   13. Central service agency
   14. Community Perinatal Center-Intermediate
   15. Community Perinatal Center-Intensive
   16. Regional Perinatal Center
   17. Assisted living program
   18. Any service for which regionalization criteria or health planning regulations have been developed.

EXHIBIT 2
Examples of Major Moveable Equipment

Cardiac catheterization laboratory equipment

EXHIBIT 3
Certificate of Need Review

BED-RELATED HEALTH CARE FACILITY/SERVICES

NEW/EXPANSION	TYPE OF REVIEW
Adult family care	Exempt
Assisted living program	Expedited
Assisted living residence	Expedited
Burn center, unit or program	Full
Comprehensive personal care home	Expedited
General hospital	Full
Hospital-based subacute care unit	Exempt
ICU/CCU beds (adult)	Exempt
Medical detoxification program (hospital based)	Exempt
Medical/surgical	Exempt
Long term acute care	Expedited
Long-term care facility	
Additions greater than 10 beds or 10 percent, whichever is less in accordance with N.J.S.A. 26:2H-7.2	Exempt
General long-term care	Full
Pediatric long-term care	Full
Specialized long-term ventilator care	Full
Specialized long-term care for behavior management	Full
Statewide restricted admissions facility	Expedited
Obstetric service	Exempt
Pediatric service (excluding intensive/critical care)	Exempt
Pediatric service (intensive/critical care)	Full
Psychiatric hospital	
Acute	Full
Intermediate and special	Full
Rehabilitation hospital (in-patient)	Full
Residential health care facility	Exempt
Residential substance abuse treatment facility	Exempt
Special hospital	Full
Specialty acute care children's hospital	Full
DECREASE IN BEDS	Exempt
REPLACEMENT OF BEDS	Exempt

RELOCATION OF LICENSED BEDS OR AN ENTIRE SERVICE SUBJECT TO CN REVIEW

Within the same planning region in accordance with N.J.A.C. 8:33-3.4(a)3…….	Expedited

RELOCATION OR REPLACEMENT OF AN ENTIRE LICENSED BED RELATED FACILITY SUBJECT TO CN REVIEW

General hospital/within or outside county.....	Full
All other/within same planning region in accordance with N.J.A.C. 8:33-3.5(a)4.....	Expedited
All other/at the same site in accordance with N.J.A.C. 8:33-3.5(a)2	Exempt

TERMINATION/DISCONTINUANCE OF LICENSED BEDS, SERVICES OR FACILITIES

General hospital (all beds/services)……...	Full
General hospital (some beds/services)……...	
No access problems……...	Exempt
Access problems……	Expedited
All other health care facilities……..	Exempt

NON-BED RELATED HEALTH CARE SERVICES/FACILITIES

NEW/EXPANSION

Ambulatory care	Exempt
Ambulatory surgery facility.....	Exempt
Birth center	Exempt
Bone marrow transplant/harvesting including stem cell	Full
Cardiac diagnostic services/invasive (catheterization)	
New full service	Expedited
New or addition to low risk.....	Expedited
Addition of catheterization equipment to full service	Exempt
Replacement of equipment	Exempt
Cardiac surgical service.....	Full
New	Full
Addition of operating rooms to licensed cardiac surgery service.....	Exempt
Cardiac transplant service.....	Full
Central service agency.....	Full
Comprehensive outpatient rehabilitation facility...	Exempt
Emergency medical service helicopter	Full

Extracorporeal shock wave lithotripter (kidney &/or biliary)	Exempt
Gamma knife	Exempt
Hemodialysis and peritoneal dialysis	Exempt
Home health agency	Full
Hyperbaric chamber	Exempt
Kidney transplant service	Full
Lung transplant service	Full
Magnetic resonance imaging/nuclear magnetic resonance	Exempt
Megavoltage radiation oncology/linear accelerator	Exempt
Mobile intensive care or advanced life support service (new)	Full
Mobile intensive care unit (additions to vehicles or hours of operation)	Exempt
Operating rooms	Exempt
Organ bank	Full
Organ transplantation/procurement	Full
Perinatal service: Maternal and Child Health Consortia	
New service	Full
Change in membership	Full
Perinatal service: Regional Perinatal Center, CPC-Intensive CPC-Intermediate	
New service and designation	Full
Change in designation	Full
Increased number of intermediate or intensive bassinets	Full
Perinatal service: CPC-Basic, CPC-Birth Center Designation	Exempt
Positron emission tomography scanning	Exempt
Satellite emergency department	Exempt
Special child health clinics providing tertiary services	Exempt
Trauma service	Full
Any other new health/medical care technologies that the Department identifies as having a Statewide or regional impact	Full
CAPITAL IMPROVEMENTS AND RENOVATIONS TO HEALTH CARE FACILITIES	Exempt
REPLACEMENT OF EXISTING NON-BED RELATED HEALTH CARE FACILITY/SERVICE	Exempt

TRANSFER OF OWNERSHIP

LICENSED FACILITY	
General hospital	Full
All other	Exempt
UNIMPLEMENTED CERTIFICATE OF NEED	
Less than 10 percent transfer of stock	Expedited
Limited partnership interests	Expedited
Membership of nonprofit corporations	Expedited
Death of applicant	Expedited
Change in entity without change in principals	Expedited
All other changes	Not Accepted

UNIMPLEMENTED CERTIFICATE OF NEED

CHANGE IN COST in accordance with N.J.A.C. 8:33-3.9(a)	Exempt
CHANGE IN FINANCING	Exempt
CHANGE IN SCOPE	
Increase in beds/MME/services	
Not subject to CN review	Exempt
Subject to CN review	Not Accepted
Decrease in beds/MME/services	Exempt
CHANGE OF SITE	
Within same county in accordance with N.J.A.C. 8:33-3.9(b)1.3	Exempt
Within same planning region in accordance with N.J.A.C. 8:33-3.9(b)2.4	Expedited
EXTENSION OF TIME	Expedited

CN = Certificate of Need
CPC=Community Perinatal Center
MME = Major Moveable Equipment